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Patient and Public involvement in health research in low and middle-income countries: a narrative review

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-026514
Article Type:	Research
Date Submitted by the Author:	25-Sep-2018
Complete List of Authors:	Cook, Natalie; University of york , Health Sciences; Hull York Medical School, Siddiqi, Najma; University of York, Psychiatry, Hull York Medical School, York and Bradford District Care NHS Foundation Trust, Bradford, UK Twiddy, Maureen; University of Hull, Institute of Clinical and Applied Health Research; University of Leeds , Institute of Health Sciences
Keywords:	International health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, STATISTICS & RESEARCH METHODS, QUALITATIVE RESEARCH

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Patient and Public involvement in health research in low and middle-income countries: a narrative review

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Word Count: 2638

Abstract:

Objectives

Patient and public involvement (PPI) is argued to lead to higher quality health research, which is more relatable to and helps empower the public. As the emphasis towards patient and public involvement in research continues to grow in high income countries (HIC), the extent and impact of PPI in low and middle-income countries (LMIC) remains unclear.

Results

Following a literature search, data were extracted, analysed for stage of research, level of involvement and impact, and then presented as a narrative synthesis; focusing on identifying different PPI strategies and frameworks as well as the impact of PPI on the research participant, community, and research process. Additionally, we considered the impact of who was undertaking the research (local or foreign research teams), on the level of involvement and reported impact.

Sixty-two studies met the inclusion criteria. The review revealed the most common stage for PPI involvement was in research planning and the most common level of involvement was collaboration. Most studies did not provide evidence of effectiveness or elaborate on the impact of PPI and they tended to report impact from the researcher’s perspective. Where impact was mentioned, this generally related to increased relevance to the community, empowerment of participants and alterations in study design. There is not enough evidence to make inferences about the relationship between stage/level of involvement and impact of PPI.

Conclusions

The literature describing approaches to and impact of PPI in LMIC health research is sparse. As PPI is now integral to many grant applications, it should be fully reported and evaluated at the end of the research project. Researchers may find it useful to consult tools when planning and reporting on PPI to help ensure that meaningful patient and public involvement is embedded throughout the research, though these may need adapting for use in LMIC.

Strengths and Limitations of this study

- We conducted an extensive systematic search of the literature along with hand searching but it is possible that studies may have been missed due to the range of terminology used to describe PPI and lack of MeSH terms for PPI in database searches.
- We did not have the resources to seek further information from authors so data was restricted to published information.
- None of the papers identified reported the impact of PPI from the perspective of the patient or public, and so any perceived benefits or challenges are missing from the existing literature.
- Publication and reporting biases might have an impact on the findings of this review but their impact cannot be estimated.

Keywords

LMIC, PPI, patient and public involvement, health research

Article Summary

Our narrative synthesis is the first to focus on PPI in LMIC. Our findings show that PPI tends to take place during the study planning stage, and takes a collaborative approach. Guidance for researchers explaining how to plan and report PPI in LMIC is urgently needed to improve quality of reporting.

Background:

Rationale

Patient and Public involvement in research can be defined as “*research being carried out ‘with’ or ‘by’ members of the public, rather than ‘to’, ‘about’ or ‘for’ them*” (INVOLVE, FAQs, 2018). The global mandate for public involvement was set by the World Health Organisation Declaration of Alma-Ata in 1978, as a step towards everyone having the ‘*right and duty to participate individually and collectively in the planning and implementation of their health care*’ (World Health Organisation, 1978).

To our knowledge, there has been one previous attempt to systematically analyse examples of PPI in research in LMIC. Semrau et al conducted a systematic review on service user involvement in mental health system strengthening, concluding that there was no evidence on how best to involve service users in mental health research in LMIC (Semrau, 2016). In our review, we broadened the search criteria to capture PPI from the whole of health research and also identify examples of PPI which may be described using different terminology.

Recently, there has been a growing interest in PPI in LMIC with the launch of the ‘International network for public involvement and engagement in health and social care research’ from Cochrane (Cochrane, 2018) and INVOLVE’s NIHR international network (INVOLVE, ‘International Working’) to drive patient and public involvement forward. Given this drive to improve PPI in LMIC, it is therefore timely to review the evidence on this important topic. The aim of this narrative review is to describe the PPI strategies and their impact reported in health research in LMIC in a narrative synthesis of the literature.

Methods

Eligibility criteria

Inclusion criteria included:

- any study design
- health research
- any age of study participants
- any language
- 1978-1 Dec 2017 (the inception date coincides with WHO Declaration of Alma-Ata)
- Evidence of patient or public involvement in research

Search strategy and study selection

A literature search was performed using EMBASE, Medline, PsychINFO along with hand-searching references, grey literature, google search and expert advice. After consideration, it was decided to include a wide range of terminologies to capture studies that had PPI but did not necessarily define it as such. For example, Community Based Participatory Research (CBPR) is commonly used in LMIC and when the inclusion criteria were met, these studies were included in the analysis. CBPR is a term used to describe research which ideally stems from the local community and continues to involve all partners, in an equal way, throughout the entire research process, and so closely aligns to ‘user led’

research (Minkler, 2005). Studies focusing only on community engagement were excluded unless they specifically included patients or public in the design of the study. Furthermore, since the study design or topic was not our focus, we included studies of any design from all disciplines; information about PPI may be relevant for health research regardless of discipline.

Search terms were decided with the help of an information specialist (KW); checking for inclusion of key papers known to the team and refining the balance between feasibility and inclusivity. Search terms included:

Patient & Public (patient, public, service-user, care-giver, family, consumer, lay person, advocacy group, NGO, citizen, community, client, consumer, survivor, stakeholder, relative)

AND

Involvement (community participation, patient participation, community based participatory research, PPI, collaborat*, engag*, partner*)

AND

Low and Middle-Income Country (developing country, list of individual countries as per World Bank – Jan 2018)

AND

Health Research (health services research, biomedical research, research design, qualitative)

A total of 1969 studies were identified in the literature search (see figure 1 for PRISMA flow diagram). After duplicate removal, 1314 abstracts (and full papers, if required) were screened based on the inclusion criteria by one researcher (NC), resulting in 1184 studies being excluded (see figure 2 for details of exclusion criteria). 61 studies from 34 different countries were included in the narrative synthesis. No quality assessment was performed on the studies as the purpose of the review was to identify strategies and impact rather than appraise the quality of research.

Figure 1: PRISMA flow diagram

Figure 2: Exclusion Criteria

Data Extraction and Coding

All studies meeting the inclusion criteria were read in full by one researcher (NC) and relevant data, relating to stage and level of involvement as well as impact was extracted using a structured data

extraction sheet and a coding framework was developed using an inductive approach to examine the impact of PPI on research. Extracted data were then independently coded by a second lay researcher (RK) to validate the data being collected. Discrepancies in how the coding framework was applied to extracted data were referred to a third independent reviewer (MT) for review and consensus reached.

In this review, categories for stages of the research cycle were based on those described by the National Institute of Health Research (see figure 3, NIHR Research Cycle):

Figure 3: NIHR Research Cycle

For coding purposes, stages were grouped into 4 groups - pre-research (identifying and prioritising, commissioning); planning (designing and managing); undertaking research (undertaking); post-research (disseminating, implementing, evaluating impact). Levels of involvement were coded using NIHR definitions (NIHR, 'Approaches to public involvement in research):

1. Consultation, which is asking the public for their views and using them to inform decision making
2. Collaboration, which consists of an 'ongoing partnership' between research team and members of the public, 'where decisions about the research are shared'
3. User controlled research, which is 'actively controlled, directed and managed by' the public

Patient and Public Involvement

This narrative review was supported by RK, who is a lay researcher who assisted as an independent coder.

Results

The review found that the most common stage to have PPI involvement was the planning stage (51) followed by undertaking (30), post research (27) and finally pre-research (18). Regarding level of involvement, 37 studies were classed as collaboration with only 4 being classed as user controlled and 20 as consultation (see appendix 1 for list of papers).

Studies with consultation level involvement often had some form of community advisory committee to inform the community about different aspects of the research and sometimes seek their opinion on the research objectives, design and implementation. Mushi describes presenting preliminary

findings and intervention packages in village meetings as part of the consultation process (Mushi, 2010). Similarly, Owolabi reports using a task force which included representatives of the Nigerian Stroke Society to *'review the progress of the community participatory research process and make recommendations about any local adaptations to facilitate its effectiveness'* (Owolabi, 2014; 34).

Collaboration level involvement had varying strategies; some studies described a partnership between researcher and advocacy group(s) whilst others formed community advisory boards. Bradley's research started after the community voiced concerns to community health workers (CHW) about the increasing prevalence of hypertension and diabetes in their community (Bradley and Puoane, 2007.) Following this, a meeting was held with the local community health committee and community leaders. Aims were formulated with the intention of engaging CHWs in many aspects of the research process including data collection, analysis, and dissemination. Zola reported that the *'community based organisation members (CBO), people living with HIV (PLHIV) and researchers were involved, in an equitable partnership'* (Zola, 2014, 276) Community members were trained in research methods and ethics, and then involved in developing the questionnaire and conducting the interviews (Zola, 2014).

Finally, looking at user-controlled research; common strategies included community initiated research, involvement in the entire research project, from pre-research through to evaluation and ongoing involvement from peer researchers (Aitaoto, 2015; Hann, 2015; Jongudomkarn, 2014; Hayashi et al, 2012). Hayashi describes CBPR which was led by a group of active and former drug users (Thai Drug Users' Network) who were involved in the whole study from design through to analysis and dissemination. Similarly, Jongudomkarn's study was initiated by community members via a forum and the women were involved in the entire research process right through to the action plan and evaluation (Jongudomkarn, 2014).

The most commonly cited impacts of PPI included increased relevance to the community, empowerment of participants and alterations in trial design. Foster reported that the research team, consisting of US nurses, Dominican nurses and community leaders continued to meet after the research had ended to drive improvement; hence empowering the team (Foster, 2010). After the conclusion of Jongudomkarn's research, the women involved became the *'resource persons responsible for alcohol consumption campaigns'* (Jongudomkarn, 2014; 7344). Liu explained that the community steering group modified the wording of some of the translations to ensure cultural relevance for a Mandarin-speaking population (Liu, 2011). Following feedback from the community

reference team, Mosavel decided to *‘refocus the research from cervical cancer to ‘cervical health’* (Mosavel, 2005; 2577).

Another benefit reported was improved quality of results; Bowling commented that the *‘partnership with local researchers and community partners strengthened the quality of the findings through their involvement in design, recruitment and interpretation phases’* (Bowling et al, 2016; 826). Reflecting on higher levels of engagement in the community, Grinker described how PPI *‘facilitates the crucial recruitment phase as well as participant retention by limiting or managing negative views or misunderstandings of the researchers, procedures or goals of the study’* (Grinker, 2012; 203). Another impact to consider is increased community trust and improved community-researcher relations. In Simwanga’s South African study, community advisory board members provided a *‘protective role for community members’* and also helped *‘resolve tensions between researchers and community’* (Simwanga, 2016: 197,199). Furthermore, PPI can help challenge common community misconceptions and stigma; Adhikari noted that having local villagers involved in their malaria study helped tackle rumours in the community (Adhikari, 2017). Finally, some studies reported on the difficulties of PPI; largely focusing on the extra time and money required to have PPI in their study (Hayashi, 2012; Fujiwara, 2005; Karmaliani, 2009; Kobeissi, 2011). It is important to note that most of the impact reported is from the researcher’s perspective and was often reported as an aim rather than an evidence based outcome of PPI. In some cases, impact was not reported at all.

Finally, we thought it was important to consider whether the study authors were from the study country. The vast majority of studies (n=57), had at least one author from the study country; 43 of these were in partnership with researchers from high income countries. Only 5 studies were conducted without the input of local researchers. Although it is difficult to be certain from study reports, we estimate 10 of the 61 studies included Non-Governmental Organisation (NGO) or advocacy group members as authors.

Discussion

This review reveals that researchers are using PPI at different stages and levels in health research taking place in LMIC, highlighting that regardless of the subject or type of research, PPI can be integrated into the research process and may consequently have an impact on both the research and the individuals involved. There is a lack of reporting of PPI strategies and impact; those studies which do, are still largely reporting impact from the researcher perspective. It is important to state that the finding of poor reporting is not unique to research conducted in LMIC. Both Mockford et al

and Brett et al, have identified issues with the evidence base behind PPI as well as the poor quality of reporting which is essentially limiting our understanding of PPI impact (Mockford et al, 2011; Brett et al, 2010).

Our review identified that most PPI is taking place during the planning stage of research, which is in contrast to a similar review, not focused on LMIC, which found more examples of PPI in the execution phase (Domecq et al, 2014). By incorporating PPI into the planning stage, the studies are meeting best practice NIHR recommendations but perhaps, in addition, LMIC researchers gain an advantage by identifying topics relevant to the community and gaining access and acceptance into the community, ultimately enabling the progression of the research project; this is especially important when part of the research team are not local researchers.

Earlier research looking at impact of PPI in the UK and Europe aligns closely with the findings of our review of LMICs, suggesting that although the context may be quite different, benefits can be realised from PPI in LMICs. Brett et al discuss the impact of PPI throughout the research cycle suggesting that PPI in the planning stage can help identify and prioritise topics according to relevance; in the implementation stage, it can help participant recruitment and researcher-participant rapport and during analysis and write-up, it allows findings to be interpreted from a user perspective and can also assist with research dissemination (Brett, 2012). Brett et al also reported similar challenges as identified in our review, such as time and cost, whilst also reflecting on the impact of tokenistic involvement and scientific/ethical conflicts, along with more specific issues relating to group dynamics (Brett, 2012). Brett and colleagues concluded that by providing good training and creating defined roles in a positive supportive environment with mutual trust and respect, PPI will have more potential for impact (Brett, 2012). Similarly, the EPIC study encouraged researchers to set clear goals, well developed plans and advocate for individuals to be involved early in the research in a responsive, managerial way rather than solely having a general oversight, more often seen in membership of steering committee, an approach which was widely used in the studies we identified in our review (Gamble, 2015).

Despite the increased focus on PPI, there is a lack of standardisation in designing and evaluating PPI frameworks and strategies. Over the last decade, researchers have been developing PPI toolkits but as yet, none have been adopted as a standardised tool (Bagley, 2016; Cartwright and Crowe, 2011; Scottish Health Council, 2018). One of the more recent is the GRIPP2 checklist, which was developed following a systematic review and Delphi study to assist with the reporting of patient and public

involvement in research, with the aim of improving quality and transparency of the PPI evidence base (Staniszewska, 2017). The authors recommend that the checklist should be used prospectively in research design and retrospectively in evaluation. The GRIPP2 short form includes sections on aims, method, results (both positive and negative), discussion (impact) and reflection – each of these areas requiring information specific to PPI (Staniszewska, 2017). However, it is important to note that this tool, though developed for international use, was developed from a high-income country perspective and though there are similarities, there are also complexities specific to LMIC that need to be considered; particularly the variations in research infrastructure, cultural differences, and often, lower research budget.

Conclusion

We hope to contribute to the continued development of pre-existing PPI tools used in the reporting of PPI strategies for LMICs; to clearly evidence the level, stage and impact of the PPI. To improve the evidence base for impact of PPI, authors should consider providing details of their PPI strategy alongside an evaluation of impact, capturing the voice of the patient and public to show how it has affected them as individuals as well as the wider community.

Acknowledgements

We would like to thank Kath Wright for her support with the literature search and Richard Kenyon for his help with data analysis.

Author Contributions

NC, NS and MT designed the study. NC extracted, analysed, synthesised and coded the data. NC wrote the first draft of the manuscript. NS and MT contributed to the interpretation of results and the writing of the manuscript for publication.

Funding Statement

This research was led by an NIHR Academic Clinical Fellow. There was no funding for the research.

Competing Interests Statement

The authors have no competing interests.

Data Sharing Statement

Studies included in the research can be found in Appendix 1.

References

Adhikari, B et al. (2017). *Factors associated with population coverage of targeted malaria elimination (TME) in southern Savannakhet Province, Lao PDR*. Malaria Journal, 16:424

Aitaoto, N et al. (2015). *Formative research to inform nutrition interventions in Chuuk and the U.S. Pacific*. Journal of the Academy of Nutrition and Dietetics, 115(6): 947-53

An international network for public involvement and engagement in health and social care research [ONLINE] <http://www.cochrane.org/news/international-network-public-involvement-and-engagement-health-and-social-care-research>. Accessed 12 June 2018

Bagley, HJ et al. (2016). *A patient and public involvement (PPI) toolkit for meaningful and flexible involvement in clinical trials*. Research Involvement and Engagement, 2:15

Bradley, HA. Puoane, T. (2007). *Prevention of hypertension and diabetes in an urban setting in South Africa: Participator Action Research with Community Health Workers*. Ethnicity and Disease, 17(1): 49-54

Brett J et al (2010). *The PIRICOM Study: A Systematic Review of the Conceptualisation, Measurement, Impact and Outcomes of Patients and Public Involvement in Health and Social Care Research*. Warwick: University of Warwick

Brett, J et al. (2012). *Mapping the impact of patient and public involvement on health and social care research: a systematic review*. Health Expectations, 17 (5): 637-650

Bowling, J et al. (2016). *Perceived health concerns among sexual minority women in Mumbai, India: an exploratory qualitative study*. Culture, Health and Sexuality, 18(7): 826-840

Cartwright, J. Crowe, S. (2011) *Patient and Public Involvement Toolkit*. BMJ Books: place Cochrane (March 2018).

Domecq, JP. (2014). *Patient engagement in research: a systematic review*. BMC Health Services Research, 14:89

Foster, J et al (2010). *A Community-Based Participatory Research approach to explore community perceptions of the quality of maternal-newborn health services in the Dominican Republic*. Midwifery, 26(5): 504-11

Fujiwara, T et al (2005). *The spread of drug abuse in rapidly urbanizing communities in Vientiane, Lao People's Democratic Republic*, Health Promotion International, 20(1): 61-8

Gamble, C et al (2015). *An evidence base to optimise methods for involving patient and public contributors in clinical trials: a mixed methods study*. Health Service and Delivery Research (339) NIHR Journals Library: Southampton.

Grinker, RR et al. (2012). *"Communities" in Community Engagement: Lessons Learned from Autism Research in South Africa and South Korea*. Autism Research, 5(3): 201-210

Hann, K et al (2015). *Factors for success in mental health advocacy*, Global Health Action: 8

Hayashi, K et al (2012), *Collective Empowerment While Creating Knowledge: A Description of a Community-Based Participatory Research Project With Drug Users in Bangkok, Thailand*. Substance Use and Misuse, 47(5): 502-510

INVOLVE (no date). *International Working* [ONLINE] <http://www.invo.org.uk/current-work/international-working/>. Accessed 12 June 2018

INVOLVE. 2018. *Frequently Asked Questions* [ONLINE] Available at <http://www.invo.org.uk/frequently-asked-questions/>. [Accessed 12 June 2018]

Jongudomkarn, D (2014). *A volunteer alcohol consumption reduction campaign: participatory action research among Thai women in the Isaan region*. Asian Pacific Journal of Cancer Prevention, 15(17): 7343-50

Karmaliani, R et al. (2009), *Applying community-based participatory research methods to improve maternal and child health in Karachi, Pakistan*. Nursing Outlook, 57(4): 204-9

Kobeissi, L et al (2011). *Evaluating a Community Based Participatory Approach to Research with Disadvantaged Women in the Southern Suburbs of Beirut*. Journal of Community Health, 36(5): 741-7

Liu, J et al (2011). *Community-based participatory research (CBPR) approach to study children's health in China: Experiences and reflections*. International Journal of Nursing Studies, 48(7): 904-913

Minkler, M. (2005) *Community-based research partnerships: Challenges and opportunities*. Journal of Urban Health, 82 (suppl 2), ii3-ii12

Mockford C et al (2011). *The impact of patient and public involvement on UK NHS healthcare: a systematic review*. International Journal for Quality in Health Care, 24 (1), 28-38

Mosavel, M et al (2005). *Community-based participatory research (CBPR) in South Africa: Engaging multiple constituents to shape the research question*, Social Science and Medicine, 61(12): 2577-87

Mushi, D. (2010). *Effectiveness of community based safe motherhood promoters in improving the utilization of obstetric care. The case of Mtwara Rural District in Tanzania*. BMC Pregnancy and Childbirth; 10:14

National Institute of Health Research (no date), *The Research Cycle*, [ONLINE] <https://www.nihr.ac.uk/patients-and-public/how-to-join-in/the-research-cycle/>. Accessed 12 June 2018.

National Institute of Health Research (no date), *Approaches to public involvement in research*. <http://www.invo.org.uk/posttypesresource/approaches-to-public-involvement/>. Accessed 12 June 2018.

Owolabi, MO. (2014). *Tailored Hospital-based Risk reduction to Impede Vascular Events after Stroke (THRIVES) study: qualitative phase protocol*. Critical Pathways in Cardiology, 13(1): 29-35.

Scottish Health Council (June 2018). *The Participation Toolkit* [ONLINE] http://www.scottishhealthcouncil.org/patient_public_participation/participation_toolkit/the_participation_toolkit.aspx#.VZvZybFwblU. Accessed 12 June 2018

Semrau, M et al (March 2016). *Service user and caregiver involvement in mental health system strengthening in low-and middle-income countries*. BMC Health Services Research, 16:79

Simwinga, M et al (2016). *Implementing Community Engagement for Combination Prevention: Lessons Learnt From the First Year of the HPTN 071 (PopART) Community-Randomized Study*. Current HIV/AIDS Report, 13 (4): 194-201

Staniszewska, S et al (2017). *GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research*. British Medical Journal: 358

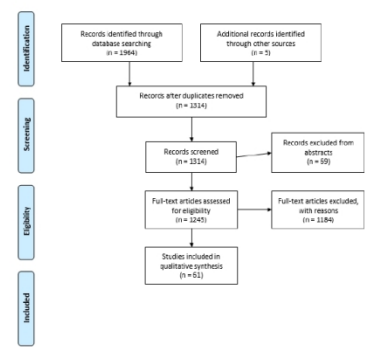
World Health Organisation. (1978). *Declaration of Alma Ata: Report of the International Conference on Primary Health Care*, Geneva

Zola, EK. (2014), *Factors associated with HIV voluntary disclosure of people living with HIV to their steady sexual partner in the Democratic Republic of the Congo: results from a community-based participatory research*. The Pan-African Medical Journal, 14 (19)

Images

Figure 3, NIHR Research Cycle, NIHR Involve, <http://www.involve.nihr.ac.uk>.

Figure 1: PRISMA Flow diagram



PRISMA Flow Diagram

437x618mm (72 x 72 DPI)

Figure 2: Exclusion Criteria

Not a LMIC	263
Not health research	247
No PPI	358
PPI Theory	157
Ethics Research	101
Patient/Community Engagement	46
Service Development	10
Not in English	1
Duplicate (not picked up in initial duplicate removal)	1
Total = 1184	

Exclusion Criteria

437x618mm (72 x 72 DPI)

Figure 3: NIHR Research Cycle



NIHR Research Cycle
437x618mm (72 x 72 DPI)

Appendix 1: List of Papers	
Author (s)	Study
Consultation	
Adhikari, B et al (2017)	Factors associated with population coverage of targeted malaria elimination (TME) in southern Savannakhet Province, Lao PDR. <i>Malaria Journal</i> , 16:424
Campbell M, et al (2015)	Exploring researchers' experiences of working with a researcher-driven, population-specific community advisory board in a South African schizophrenia genomics study, <i>BMC medical ethics</i>
Corneli, AL et al (2007)	Involving communities in the design of clinical trial protocols: The BAN Study in Lilongwe, Malawi. <i>Contemporary Clinical Trials</i> , 28 (1), 59-67
Decat, P et al (2013)	Community embedded reproductive health interventions for adolescents in Latin America: development and evaluation of a complex multi-centre intervention. <i>BMC Public Health</i> , 13:31
Eftekhari, MB et al (2014)	Mental Health Priorities in Iranian Women: Overview of Social Determinants of Mental Health. <i>Iran J Psychiatry</i> , 9(4): 241-247
Ellen, JM et al (2010)	Community Engagement and Investment in Biomedical HIV Prevention Research for Youth: Rationale, Challenges, and Approaches. <i>J Acquir Immune Defic Syndr</i> . 54 Suppl 1: S7-11
Freudenthal, S et al (2006)	School-based prevention of schistosomiasis: Initiating a participatory action research project in northern Tanzania. <i>Acta Tropica</i> , vol 100, issues 1-2, 79-87
Maman, S et al (2009)	Using participatory mapping to inform a community-randomized trial of HIV counseling and testing. <i>Field Methods</i> , 21(4):368-87
Mellins, CA et al (2104)	Adapting Evidence-Based Interventions to Meet the Needs of Adolescents Growing Up with HIV in South Africa: The VUKA Case Example. <i>Glov Soc Welf</i> , 1(3):97-110
Mushi, D et al (2010)	Effectiveness of community based safe motherhood promoters in improving the utilization of obstetric care. The case of Mtwara Rural District in Tanzania. <i>BMC Pregnancy and Childbirth</i> , 10:14
Nichter, M et al (2015)	Developing a smoke free homes initiative in Kerala, India. <i>BMC Public Health</i> ; 15:480
Ntshanga, SP et al (2010)	Establishment of a Community Advisory Board (CAB) for tuberculosis control and research in the Inanda, Ntuzuma and KwaMashu (INK) area of KwaZulu-Natal, South Africa. <i>Health Policy</i> ; 95(2-3):211-5
Olaitan, PB et al (2014)	Recruitment of Yoruba families from Nigeria for genetic research: experience from a multisite keloid study. <i>BMC Medical Ethics</i> , 15:65
Owolabi, MO et al (2014)	Tailored Hospital-based Risk reduction to Impede Vascular Events after Stroke (THRIVES) study: qualitative phase protocol. <i>Crit Pathw Cardiol</i> , 13(1):29-35
Pardo, G et al (2017)	Cultural Adaptation of an Evidence-Informed Psychosocial Intervention to Address the Needs of PHIV+ Youth in Thailand. <i>Glov Soc Welf</i> , 4:209
Remien RH, et al (2013)	Masivukeni: Development of a Multimedia Based Antiretroviral Therapy Adherence Intervention for Counselors and Patients in South Africa. <i>AIDS Behav</i> , 17(6):1979-91
Shanks, L et al (2015)	"Losing the tombola": a case study describing the use of community consultation in designing the study protocol for a randomised controlled trial of a mental health intervention in two conflict-affected regions. <i>BMC Medical Ethics</i> , 16:38
Simwinga, M et al (2016)	Implementing Community Engagement for Combination Prevention: Lessons Learnt From the First Year of the HPTN 071 (PopART) Community-Randomized Study. <i>Curr HIV/AIDS Rep</i> , 13(4):194-201
South, A et al (2016)	Models and impact of patient and public involvement in studies carried out by the Medical Research Council Clinical Trials Unit at University College London: findings from ten case studies. <i>Trials</i> , 17:376
Tindana, PO et al (2007)	Grand Challenges in Global Health: Community Engagement in Research in Developing Countries. <i>PLoS Med</i> 4(9):e273
Consultation	
Adams, LV et al (2016)	Mining for Solutions: Final report on research designed to engage Southern African Miners, Ex-miners, managers and policymakers, clinicians, and communities on tuberculosis to improve healthcare delivery. <i>Annals of Global Health</i> . 82(3), p.328
Ahari, SS et al (2012)	Community based needs assessment in an urban area; A participatory action research project. <i>BMC Public Health</i> , 12:161

Anticona, C et al (2013)	Easier said than done: challenges of applying the Ecohealth approach to the study on heavy metals exposure among indigenous communities of the Peruvian Amazon. BMC Public Health, 13: 437
Asante, KP et al (2013)	Community engagement in biomedical research in an African setting: the Kintampo Health Research Centre experience, BMC Health Services Research, 13:383
Balagopal, P et al (2012)	A Community-Based Participatory Diabetes Prevention and Management Intervention in Rural India Using Community Health Workers. Diabetes Educ, 38 (6): 822-34
Bang & Bang (1991)	Community participation in research and action against alcoholism. World Health Forum; 12(1): 104-9
Baptiste, DR et al (2006)	Community Collaborative Youth-Focused HIV/AIDS Prevention in South Africa and Trinidad: Preliminary Findings. J Paediatric Psychology, 31(9): 905-16
Bisung, E et al (2015)	Using Photovoice as a Community Based Participatory Research Tool for Changing Water, Sanitation, and Hygiene Behaviours in Usoma, Kenya. BioMed Research International, vol. 2015, Article ID 903025, 10 pages.
Blanchard, AK et al (2017)	Pursuing Authenticity From Process to Outcome in a Community-Based Participatory Research Study of Intimate Partner Violence and HIV Vulnerability in North Karnataka, India. Qual Health Res. 27(2):204-214
Bowling, J et al (2016)	Perceived health concerns among sexual minority women in Mumbai, India: an exploratory qualitative study. Cult Health Sex, 18(7):826-40. doi: 10.1080/13691058.2015.1134812.
Bradley, HA et al (2007)	Prevention of hypertension and diabetes in an urban setting in South Africa: Participatory Action Research with Community Health Workers, Ethn Dis. 17(1):49-54.
Brooks, C et al (2007)	Introducing visual participatory methods to develop local knowledge on HIV in rural South Africa. BMJ Glob Health. 28;2(3)
Ekirapa-Kiracho, EE et al (2016)	Unlocking community capabilities for improving maternal and newborn health: participatory action research to improve birth preparedness, health facility access, and newborn care in rural Uganda. BMC Health Services Reseach. BMC series2016 (Suppl 7:638)
Foster, J et al (2010)	A Community-Based Participatory Research approach to explore community perceptions of the quality of maternal-newborn health services in the Dominican Republic. Midwifery, 26(5): 504-11
Fujiwara, T et al (2005)	The spread of drug abuse in rapidly urbanizing communities in Vientiane, Lao People's Democratic Republic. Health Promot Int, 20(1), 61-8
Gaudine, A et al (2007)	An Action Research Approach to Developing Culturally Relevant Interventions: The Stigma of HIV in a Vietnamese Community. Can J Nurs Res, 39(3): 195-7
Grinker, RR et al (2012)	"Communities" in Community Engagement: Lessons Learned from Autism Research in South Africa and South Korea. Autism Res, 5(3): 201-210
Jacobs, B et al (2003)	Community participation in externally funded health projects: Lessons from Cambodia. Health Policy Plan; 18(4):399-410
Karmaliani, R et al (2009)	Applying community-based participatory research methods to improve maternal and child health in Karachi, Pakistan. Nurs Outlook; 57(4):204-9
Kobeissi, L et al (2011)	Evaluating a Community Based Participatory Approach to Research with Disadvantaged Women in the Southern Suburbs of Beirut. J Community Health, 36(5): 741-7
Lee, K et al (2015)	Sexual and reproductive health services for women with disability: a qualitative study with service providers in the Philippines. BMC Womens Health, 15:87
Liu, J et al (2011)	Community-based participatory research (CBPR) approach to study children's health in China: Experiences and reflections. Int J Nurs Stud; 48(7):904-13
Lorway, R et al (2014)	Going beyond the clinic: confronting stigma and discrimination among men who have sex with men in Mysore through community-based participatory research. Critical Public Health, 24(1); 73-87
Makhoul, J et al (2014)	Community-based participatory research in complex settings: clean mind—dirty hands. Health Promot Int, 29(3):510-7
Massey, PD et al (2012)	TB questions, East Kwaio answers: community-based participatory research in a remote area of Solomon Island. Rural Remote Health, 12:2139
Morisky, DE et al (2010)	Reducing sexual risk among Filipina female bar workers: effects of a CBPR-developed structural and network intervention. AIDS Educ Prev, 22(4): 371-85
Mosavel, M et al	Community-based participatory research (CBPR) in South Africa: Engaging multiple constituents

(2005)	to shape the research question. Soc Sci Med; 61(12):2577-87
Murray, LK et al (2013)	Identification, modification, and implementation of an evidence-based psychotherapy for children in a low-income country: the use of TF-CBT in Zambia. Int J Ment Health Syst; 7:24
Nyamathi, AM et al (2010)	Perceptions of Women Living with AIDS in Rural India Related to the Engagement of HIV-Trained Accredited Social Health Activists for Care and Support. J HIV AIDS Soc Serv, 9(4):385-404
Pazoki R, et al (2007)	Effects of a community-based healthy heart program on increasing healthy women's physical activity: a randomized controlled trial guided by Community-based Participatory Research (CBPR). BMC Public Health, 7:216
Puffer ES, et al (2013)	Developing a Family-Based HIV Prevention Intervention in Rural Kenya: Challenges in Conducting Community-Based Participatory Research. J Empir Res Hum Res Ethics, 8(2):119-28
Ramjee G, et al (2010)	Experiences in conducting multiple community-based HIV prevention trials among women in KwaZulu-Natal, South Africa. AIDS Res Ther, 7:10
Rhodes, SD et al (2015)	The ecology of sexual health of sexual minorities in Guatemala City. Health Promot Int, 30(4):832-42
Twine, R et al (2016)	Involvement of stakeholders in determining health priorities of adolescents in rural South Africa. Global Health Action; 9
Vaughan, C et al (2015)	W-DARE: a three-year program of participatory action research to improve the sexual and reproductive health of women with disabilities in the Philippines. BMC Public Health; 15:984
Wattayay, N et al (2015)	Applying Qualitative Data Derived from a Rapid Assessment and Response (RAR) Approach to Develop a Community-based HIV Prevention Program for Adolescents in Thailand. J Assoc Nurses AIDS Care; 26(5):602-12
Zola, EK et al (2014)	Factors associated with HIV voluntary disclosure of people living with HIV to their steady sexual partner in the Democratic Republic of the Congo: results from a community-based participatory research. Pan Afr Med J; 19:276. doi:10.11604/pamj.2014.19.276.5304
User-Led	
Aitaoto, N et al (2015)	Formative research to inform nutrition interventions in Chuuk and the U.S. Pacific. J Acad Nutr Diet, 115 (6): 947-53
Hann, K et al (2015)	Factors for success in mental health advocacy. Glob Health Action, 17:8
Hayashi, K et al (2012)	Collective Empowerment While Creating Knowledge: A Description of a Community-Based Participatory Research Project With Drug Users in Bangkok, Thailand. Subs Use Misuse, 47(5):502-510
Jongudomkarn, D (2014)	A Volunteer Alcohol Consumption Reduction Campaign: Participatory Action Research among Thai Women in the Isaan Region. Asian Pac J Cancer Prev. 2014;15(17):7343-50.

BMJ Open

Patient and Public Involvement in Health Research in Low and Middle-Income Countries: a systematic review

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-026514.R1
Article Type:	Research
Date Submitted by the Author:	02-Jan-2019
Complete List of Authors:	Cook, Natalie; University of York , Health Sciences; Hull York Medical School, Siddiqi, Najma; University of York, Psychiatry, Hull York Medical School, York and Bradford District Care NHS Foundation Trust, Bradford, UK Twiddy, Maureen; University of Hull, Institute of Clinical and Applied Health Research; University of Leeds , Institute of Health Sciences Kenyon, Richard
Primary Subject Heading:	Global health
Secondary Subject Heading:	Qualitative research, Research methods
Keywords:	International health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, STATISTICS & RESEARCH METHODS, QUALITATIVE RESEARCH

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Patient and Public Involvement in Health Research in Low and Middle-Income Countries: a systematic review

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Word Count: 3779

Abstract:

Objectives

Patient and Public Involvement (PPI) is argued to lead to higher quality health research, which is more relatable to and helps empower the public. We synthesised the evidence to look for examples of PPI in health research in low and middle countries (LMIC); looking at level of involvement and impact. Additionally, we considered the impact of who was undertaking the research on the level of involvement and reported impact.

Design

Systematic review

Data Sources

EMBASE, Medline, PsychINFO along with hand-searching references, grey literature, google search and expert advice.

Eligibility Criteria

Any health research with evidence of patient or public involvement, with no language restrictions dated from 1978-1 Dec 2017.

Data Extraction and Synthesis

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3 Data relating to stage and level of involvement as well as impact were extracted by one researcher
4 (NC) and a coding framework was developed using an inductive approach to examine the impact of
5 PPI on research. Extracted data were then independently coded by a second lay researcher (RK) to
6 validate the data being collected. Discrepancies were referred to a third independent reviewer (MT)
7 for review and consensus reached.
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11 12 13 **Results**

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15 Sixty-two studies met the inclusion criteria. The review revealed the most common stage for PPI
16 involvement was in research planning and the most common level of involvement was collaboration.
17 Most studies did not provide evidence of effectiveness or elaborate on the impact of PPI and they
18 tended to report impact from the researcher's perspective. Where impact was mentioned, this
19 generally related to increased relevance to the community, empowerment of participants and
20 alterations in study design.
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26 27 **Conclusions**

28 The literature describing approaches to and impact of PPI in LMIC health research is sparse.
29 As PPI is essential to conducting high quality research, it should be fully reported and evaluated at
30 the end of the research project.
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35 **Strengths and Limitations of this study**

- 36 • We conducted an extensive systematic search of the literature along with hand searching; grey
37 literature searches were limited, however, to a Google search and expert advice due to resource
38 constraints.
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- 40 • Varying use of terminology relating to PPI over time and across disciplines may mean that some
41 pertinent literature may not have been identified. The literature search was further complicated by
42 the lack of MeSH terms in database searches.
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- 44 • We did not have the resources to seek further information from authors, so data was restricted to
45 published information. Furthermore, the literature search was conducted in December 2017 so
46 recent research may be missed.
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- 48 • None of the papers identified reported the impact of PPI from the perspective of the patient or
49 public, and so any perceived benefits or challenges from these perspectives are missing from the
50 existing literature. Furthermore, papers tend to report PPI within the context of study results so
51 often lack detail in their reporting.
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- Publication and reporting biases might have an impact on the findings of this review, but their impact cannot be estimated.

Keywords

LMIC, PPI, patient and public involvement, health research

Background:

Rationale

Patient and Public Involvement (PPI) in research has been defined as “*research being carried out ‘with’ or ‘by’ members of the public, rather than ‘to’, ‘about’ or ‘for’ them*”(1). The global mandate for public involvement was set by the World Health Organisation Declaration of Alma-Ata in 1978, as a step towards everyone having the ‘*right and duty to participate individually and collectively in the planning and implementation of their health care*’(2).

Developing stronger patient and public involvement in the research and delivery of healthcare is now a central component of research proposals for funders in High Income Countries (HIC), for example the INVOLVE framework in the UK, which has been well established for over two decades. Patients and public can be actively involved in research throughout the research cycle and this can lead to higher quality health research, which meets the needs of the target community, and is relatable to, and helps empower the public. However, there are concerns that mandating PPI in grant applications can lead to “tokenistic involvement”, with academics involving patients and public in research grants simply for funding purposes, without commitment to embedding them into the research(3). The issue of tokenism seems to become even more acute when considering research undertaken in low and middle-income countries (LMIC).

As the emphasis on patient and public involvement in research continues to grow in HIC, the extent and impact of PPI in LMIC remains unclear. Research is becoming increasingly globalised, with researchers from HIC countries operating on an international basis, particularly in LMIC. This research is often supported by smaller local funders, who may not have the same requirements for PPI. HIC based health research funders expect researchers to engage with the new well established international, national and institutional sources of guidance about how to undertake research in LMIC, not least the World Medical Association’s Declaration of Helsinki(4). This has led to a move to recognise the importance of both economic and cultural differences, and so the importance of identifying locally sustainable solutions.

To our knowledge, there has been one previous attempt to systematically analyse examples of PPI in research in LMIC. Semrau et al conducted a systematic review on service user involvement in mental health system strengthening, concluding that there was no evidence on how best to involve service users in mental health research in LMIC(5). In our review, we broadened the search criteria to capture PPI from the whole of health research and also identify examples of PPI, which may be described using different terminology.

Recently, there has been a growing interest in PPI in LMIC with the launch of the 'International network for public involvement and engagement in health and social care research' from Cochrane(6) and INVOLVE's NIHR International Network(7) to drive patient and public involvement forward.

Given this drive to improve PPI in LMIC, it is timely to review the evidence on this important topic. The aim of this systematic review is to describe the PPI strategies and their impact reported in health research in LMIC in a narrative synthesis of the literature.

Methods

Eligibility criteria

Inclusion criteria included:

- any study design
- health research
- any age of study participants
- any language
- 1978-1 Dec 2017 (the inception date coincides with WHO Declaration of Alma-Ata)
- Evidence of patient or public involvement in research

Search strategy and study selection

A literature search was performed using EMBASE, Medline and PsychINFO along with hand-searching references of key articles and a Google search and expert advice for grey literature. After consideration, it was decided to include a wide range of terminologies to capture studies that had PPI but did not necessarily define it as such. For example, Community Based Participatory Research (CBPR) and Participatory Action Research (PAR) are commonly used in research and when the other inclusion criteria were met, these studies were included in the analysis. CBPR is a term used to describe research which ideally stems from the local community and continues to involve all

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partners, in an equal way, throughout the entire research process, and so closely aligns to ‘user led’ research(8). Similarly, the term Participatory Action Research (PAR) is commonly used to describe an approach which involves ‘researchers and participants working together’ often focusing on social change(9).

Studies focusing only on community engagement were excluded unless they specifically included mention of patient or public involvement in the study design or conduct. Community engagement is where ‘information and knowledge about research is provided or shared’, for example open meetings to raise awareness or using social media to share findings(10). Furthermore, since the study design or topic was not our focus, we included studies of any design from all disciplines; information about PPI may be relevant for health research regardless of study type or discipline.

Search terms were decided with the help of an information specialist (KW); checking for inclusion of key papers known to the team and refining the balance between feasibility and inclusivity. Search terms included:

Patient & Public (patient, public, service-user, care-giver, family, consumer, lay person, advocacy group, NGO, citizen, community, client, consumer, survivor, stakeholder, relative)
AND
Involvement (community participation, patient participation, community based participatory research, PPI, collaborat*, engag*, partner*)
AND
Low and Middle-Income Country (developing country, list of individual countries as per World Bank – Jan 2018)
AND
Health Research (health services research, biomedical research, research design, qualitative)

Data Extraction and Coding

All studies meeting the inclusion criteria were read in full by one researcher (NC) and relevant data, relating to stage and level of involvement as well as impact was extracted using a structured data extraction sheet and a coding framework was developed using an inductive approach to examine the impact of PPI on research. Extracted data were then independently coded by a second lay researcher (RK) to validate the data being collected. Discrepancies in how the coding framework was applied to

extracted data were referred to a third independent reviewer (MT) for review and consensus reached.

In this review, categories for stages of the research cycle were based on those described by the National Institute of Health Research (see figure 1) (11):

Figure 1: NIHR Research Cycle

For coding purposes, stages were categorised into 4 groups - pre-research (identifying and prioritising, commissioning); planning (designing and managing); undertaking research (undertaking); post-research (disseminating, implementing, evaluating impact). Levels of involvement were coded using NIHR definitions(12):

1. Consultation, which is asking the public for their views and using them to inform decision making
2. Collaboration, which consists of an 'ongoing partnership' between research team and members of the public, 'where decisions about the research are shared'
3. User controlled research, which is 'actively controlled, directed and managed by' the public

No quality assessment was performed on the studies, since the purpose of the review was to identify strategies and impact of PPI rather than focus on the type or the quality of the study undertaken. However, in order to assist with interpretation of the results, we extracted key information relating to research design (see appendix 1).

Finally, as part of the review, we designed and led a workshop attended by LMIC partners from the Improving Mental and Physical Health Multi-morbidity and Developing Research Capacity (IMPACT) Group on 12/7/18 in York. In this, we presented our findings and led a group discussion covering PPI terminology, recruitment strategies and ways of reporting impact, all of which will feed into the IMPACT study design.

Patient and Public Involvement

This narrative review was supported by RK, who is a lay researcher who assisted as an independent coder and author. Additionally, LMIC partners from IMPACT reviewed the findings and contributed to the discussion, as described above.

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Results

A total of 1969 studies were identified in the literature search (see figure 2 for PRISMA flow diagram). After duplicate removal, 1314 abstracts (and full papers, if required) were screened based on the inclusion criteria by one researcher (NC), resulting in 1184 studies being excluded (see figure 3 for details of exclusion criteria). 61 studies from 34 different countries were included in the narrative synthesis (see appendix 1 and 2).

Figure 2: PRISMA flow diagram

Figure 3: Exclusion Criteria

Many of the included studies identified their method as CBPR (n=26) or PAR (n=11). The majority of the papers were primary research; either developing or piloting interventions (n=20), qualitative research (n=17), research methods/design (n=6) or research priorities (n=4). In these papers, discussion of PPI was generally secondary to reporting the study results and often comprised only a few sentences scattered throughout the paper. The remaining papers were reflections on research (n=14), particularly focused on community advisory boards and researcher experiences. None of the studies identified would meet the criteria of the only agreed reporting framework for PPI – the GRIPP 2 (Guidance for Reporting Involvement of Patients and the Public) checklist(13).

The review found that the most common stage to have PPI involvement was the planning stage (n=51) followed by undertaking (n=30), post research (n=27) and finally pre-research (n=18). Regarding level of involvement, 37 studies were classed as collaboration with only 4 being classed as user controlled and 20 as consultation (see appendix 1)). Most studies took place in the African sub-continent, followed by India. Using World Bank criteria, the countries where the research took place could be classified as low income (n=8), lower middle income (n= 15) and upper middle-income countries (n=11)(14) (see appendix 2).

Studies with consultation level involvement often had some form of community advisory committee that was used to inform the community about different aspects of the research and sometimes seek their opinion on the research objectives, design and implementation. Mushi describes presenting preliminary findings and intervention packages in village meetings as part of the consultation process(15). Similarly, Owolabi reports using a task force which included representatives of the

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3 Nigerian Stroke Society to *'review the progress of the community participatory research process and*
4 *make recommendations about any local adaptations to facilitate its effectiveness'*(16).
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8 Collaboration level involvement had varying strategies; some studies described a partnership
9 between researcher and advocacy group(s) that ensured ongoing, two-way engagement between
10 the community and the research team, with the community identifying the healthcare problem and
11 driving forward solutions. Bradley et al research started after the community voiced concerns to
12 community health workers (CHW) about the increasing prevalence of hypertension and diabetes in
13 their community(17). Following this, a meeting was held with the local community health committee
14 and community leaders. Aims were formulated with the intention of engaging CHWs in many
15 aspects of the research process including data collection, analysis, and dissemination. Zola reported
16 that the *'community based organisation members (CBO), people living with HIV (PLHIV) and*
17 *researchers were involved, in an equitable partnership'*(18). Community members were trained in
18 research methods and ethics, and then involved in developing the questionnaire and conducting the
19 interviews(18).
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30 Finally, looking at user-controlled research; common strategies included community initiated
31 research, involvement in the entire research project, from pre-research through to evaluation and
32 ongoing involvement from peer researchers(19-22). Hayashi describes CBPR which was led by a
33 group of active and former drug users (Thai Drug Users' Network) who were involved in the whole
34 study from design through to analysis and dissemination (22). Similarly, Jongudomkarn's study was
35 initiated by community members via a forum and the women were involved in the entire research
36 process right through to the action plan and evaluation(21).
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44 The most commonly cited impacts of PPI included increased relevance to the community,
45 empowerment of participants and alterations in trial design. Foster reported that the research team,
46 consisting of US nurses, Dominican nurses and community leaders continued to meet after the
47 research had ended to drive improvement; hence empowering the team(23). After the conclusion of
48 Jongudomkarn's research, the women involved became the *'resource persons responsible for alcohol*
49 *consumption campaigns'*(21). Liu explained that the community steering group modified the
50 wording of some of the translations to ensure cultural relevance for a Mandarin-speaking
51 population(24). Following feedback from the community reference team, Mosavel decided to
52 *'refocus the research from cervical cancer to 'cervical health'*(25).
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Another benefit reported was improved quality of results; Bowling commented that the *‘partnership with local researchers and community partners strengthened the quality of the findings through their involvement in design, recruitment and interpretation phases’*(26). Reflecting on higher levels of engagement in the community, Grinker described how PPI *‘facilitates the crucial recruitment phase as well as participant retention by limiting or managing negative views or misunderstandings of the researchers, procedures or goals of the study’*(27). Another impact to consider is increased community trust and improved community-researcher relations. In Simwanga’s South African study, community advisory board members provided a *‘protective role for community members’* and also helped *‘resolve tensions between researchers and community’*(28). Furthermore, PPI can help challenge common community misconceptions and stigma; Adhikari noted that having local villagers involved in their malaria study helped tackle rumours in the community(29). Finally, some studies reported on the difficulties of PPI; largely focusing on the extra time and money required to have PPI in their study(22, 30-32). It is important to note that most of the impact reported is from the researcher’s perspective and was often reported as an aim rather than an evidence-based outcome of PPI. In some cases, impact was not reported at all.

We thought it was important to consider whether the study authors were from the study country. The vast majority of studies (93%, n=57), had at least one author from the study country; 43 of these were in partnership with researchers from high income countries. Only 5 studies were conducted without the input of local researchers. Although it is difficult to be certain from study reports, we estimate 10 of the 61 studies included Non-Governmental Organisation (NGO) or advocacy group members as authors.

Finally, we struggled to find funding guidance to identify whether PPI was a required component of the research. Some of the larger international funders mention public engagement as a concept in their material(33-36). However, many of the studies were funded by smaller local funders, for whom we were unable to find guidance.

Discussion

This review is the first to systematically review PPI in health research in LMIC. None of the studies made explicit reference to PPI as a term nor did they refer to the use of any tools or funding requirements. This could reflect an actual lack of PPI but may also reflect that research teams are simply not reporting PPI in research publications, or that researchers are using different terminology for involvement activities. It is important to state that the poor reporting of PPI is not unique to

research conducted in LMIC. Both Mockford et al and Brett et al, have identified issues with the evidence base behind PPI as well as the poor quality of reporting which is essentially limiting our understanding of PPI impact in HIC(37-38).

Nevertheless, the findings reveal that researchers are using PPI at different stages and levels in health research taking place in LMIC, highlighting that regardless of the subject, type or location of research, PPI can be integrated into the research process and may consequently have an impact on both the research and the individuals involved. There is a lack of reporting of PPI strategies and impact; those studies which do, are still largely reporting impact from the researcher perspective

Earlier research looking at the impact of PPI in the US, UK and Europe aligns closely with the findings of our review of LMIC, suggesting that although the context may be quite different, benefits can be realised from PPI in LMIC. Brett et al discuss the impact of PPI throughout the research cycle suggesting that PPI in the planning stage can help identify and prioritise topics according to relevance; in the implementation stage, it can help participant recruitment and researcher-participant rapport and during analysis and write-up, it allows findings to be interpreted from a user perspective and can also assist with research dissemination(39).

Our review identified that most PPI in LMICs takes place during the planning stage of research, which is in contrast to a similar review, not focused on LMIC, which found more examples of PPI in the execution phase(40). It is difficult to say definitively why this might be the case, but it may be related to non-LMIC researchers recognising the need to gain local knowledge in planning research in relatively unfamiliar settings.

PPI for many studies involved the setting up of community advisory groups/boards, but it is not clear if this is the most appropriate source of PPI or whether the formation of these groups acts as a barrier to meaningful engagement with the end user of the research, as the members of these groups were local community leaders, rather than those living with the particular health problem.

Furthermore, the involvement of local researchers was also apparent in the studies identified. This provided research teams with a mechanism to liaise at a grass roots level with local leaders in their local dialects and remain alert to local sensitivities. In addition, LMIC researchers may gain an advantage by identifying topics relevant to the community and gaining access and acceptance into the community, ultimately enabling the progression of the research project; this could also be used

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as a useful opportunity for research capacity building, which was mentioned in a couple of included studies (22,41).The overall relatively low level of patient involvement across the research cycle may be due to the importance, or lack of it, that funders place on PPI. Many of the studies reported in our review were supported by universities or smaller funders, for whom we were unable to find funding guidance. Larger, national and international funders do provide information about engaging communities but tend not to use the term ‘patient involvement’; rather they focus more on public engagement which, as a concept has some overlap with community engagement and PPI. For example, NIH (National Institute of Health, USA) encourages community engagement as a ‘process of working collaboratively’(34). Similarly, guidance issued by the Australian Government Research Award Scheme emphasises the importance of ‘research engagement and communication’(35) and the UNC Centre for AIDS Research has a ‘Strategic Community Engagement Education Dissemination Office’(36), with similar aims.

It is therefore unsurprising that researchers focus on the engagement of community leaders as this aligns with those goals, rather than engaging with research participants. What is unclear in the literature from LMICs is whether these were the goals of PPI in these studies, or incidental benefits. The rationale given by many of these researchers for involving people at the design stage is often related to ensuring that gatekeepers support the research, and facilitate access to the population of interest, rather than to improve the quality of the research per se(42-44). Many of the studies included in the review describe research in populations that would be defined as hard-to- reach groups, such as people with or at risk of HIV/AIDS, people with mental health problems (e.g. schizophrenia), and people with drug/alcohol problems). In the UK there is now a long established literature setting out both consumerist and democratic reasons for involving patients and the public in research(45). It could be argued that in at least some of the studies we found a third reason dominated, and that was pragmatism.

Considering ways of increasing potential for impact, Brett and colleagues reflected that good training and having clearly defined roles, in a positive supportive environment with mutual trust and respect would be beneficial(39).Similarly, the EPIC study encourages researchers to set clear goals, well developed plans and advocate for individuals to be involved early in the research in a responsive, managerial way rather than solely having a general oversight, more often seen in membership of a steering committee, (the latter approach was widely used in the studies we identified in our review)(46). Since many of the studies included in our review were CBPR, there was often a more hands-on type of involvement from participants, for example, trained community members taking

on the role of researcher(47-49) and participants shaping/piloting interventions(50-51), this type of involvement will also fulfil the secondary aim of engaging participants in the research, and perhaps develop local research capacity.

Finally, lack of standardisation in designing and evaluating PPI frameworks and strategies means it is difficult for researchers to develop a comprehensive PPI strategy. Over the last decade, researchers have been developing PPI toolkits but as yet, none have been adopted as a standardised tool(52-54). One of the more recent is the GRIPP2 checklist, which was developed following a systematic review and Delphi study to assist with the reporting of patient and public involvement in research, with the aim of improving quality and transparency of the PPI evidence base(13). The authors recommend that the checklist should be used prospectively in research design and retrospectively in evaluation. The GRIPP2 short form includes sections on aims, method, results (both positive and negative), discussion (impact) and reflection – each of these areas requiring information specific to PPI(13). However, it is important to note that this tool, though developed for international use, was developed from a high-income country perspective and though there are similarities, there are also complexities specific to LMIC that need to be considered, particularly the variations in research infrastructure, cultural differences, the power differential between researcher and researched in these contexts and often, lower research budget. Other than cultural differences and research budget, none of the other areas were explicitly considered in the included studies.

The review suggests that there are positive gains to be had from involving communities from LMIC in research, and the complexities faced by LMIC research are things that PPI can help with, through facilitating communication with communities(28,55) and adapting interventions for different cultures(50,56). PPI is still relatively new, even in countries with a well-established research tradition; it may take time for it to gain traction in countries without this tradition.

Conclusion

From this study, we can conclude that PPI does happen in LMIC health research but is generally described using different terminology and rarely, are detailed PPI strategies published. Similarly, at present the impact of PPI on both the participant and research is poorly documented. There is significant work needed to encourage closer engagement with end users of research, not just with community 'gate-keepers'.

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To improve this, LMIC research funders and journal publishers should make PPI an explicit requirement. Work also needs to be done on adapting pre-existing PPI tools for use in LMIC and encouraging their use, to clearly evidence the level, stage and impact of PPI. This will give researchers a generic format and space for reflection and will also capture the voice of the patient and public to show how it has affected them as individuals as well as the wider community.

Acknowledgements

We would like to thank Kath Wright for her support with the literature search and Joseph Clarke for his feedback on the manuscript.

We would also like to acknowledge the contribution of LMIC partners from the Improving Mental and Physical Health Multimorbidity and Developing Research Capacity (IMPACT) Group, including:

Dr Aliya Naheed, International Centre for Diarrhoeal Disease Research, Dhaka, Bangladesh

Professor Rumana Huque, ARK Foundation; Dhaka, Bangladesh

Dr Faruq Alam, National Institute of Mental Health, Dhaka, Bangladesh

Professor A H M Enayet Hussain, Ministry of Health & Family Welfare, Bangladesh

Professor Santosh Chaturvedi, National Institute of Mental Health and Neurosciences, Bangalore, India

Professor Pratima Murthy, National Institute of Mental Health and Neurosciences, Bangalore, India

Dr Arun Kandasamy, National Institute of Mental Health and Neurosciences, Bangalore, India

Dr Krishna Prasad, National Institute of Mental Health and Neurosciences, Bangalore, India

Profesor Asad Nizami, Institute of Psychiatry, Rawalpindi, Pakistan

Dr Faiza Aslam, Institute of Psychiatry, Rawalpindi, Pakistan

Author Contributions

NC, NS and MT designed the study. NC extracted, analysed, synthesised and coded the data. MT and RK independently coded the data. NC wrote the first draft of the manuscript. NS, MT and RK contributed to the interpretation of results and the writing of the manuscript for publication.

Funding Statement

This research was led by an NIHR Academic Clinical Fellow.
The study was part of a programme of research (IMPACT) that is commissioned by the National Institute of Health Research using Official Development Assistance (ODA) funding (Grant: GHR

17/63/130). The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health and Social Care.

Competing Interests Statement

The authors have no competing interests.

Data Sharing Statement

Studies included in the research can be found in Appendix 1.

References

1. INVOLVE. 2018. *Frequently Asked Questions* [ONLINE] Available at <http://www.invo.org.uk/frequently-asked-questions/>. [Accessed 12 June 2018]
2. World Health Organisation. (1978). *Declaration of Alma Ata: Report of the International Conference on Primary Health Care*, Geneva
3. Lemonsky, Fenella (2015). *Service User Involvement in Research*. The Lancet Psychiatry v2, 9:780
4. World Medical Association. *Declaration of Helsinki - Ethical Principles for Medical Research involving Human Subjects*, 2008
5. Semrau, M et al (March 2016). *Service user and caregiver involvement in mental health system strengthening in low-and middle-income countries*. BMC Health Services Research, 16:79
6. Cochrane, *An international network for public involvement and engagement in health and social care research* [ONLINE] <http://www.cochrane.org/news/international-network-public-involvement-and-engagement-health-and-social-care-research>. Accessed 12 June 2018
7. INVOLVE (no date). *International Working* [ONLINE] <http://www.invo.org.uk/current-work/international-working/>. Accessed 12 June 2018
8. Minkler, M (2005). *Community-based research partnerships: Challenges and Opportunities*. Journal of Urban Health; 82 (Suppl 2): ii3-ii12
9. Participatory Methods (no date), *Participatory Action Research*, [ONLINE], <http://www.participatorymethods.org/glossary/participatory-action-research>. Accessed 3 Dec 2018
10. National Institute of Health Research (no date), *Patient, Carer and Public Information*, [ONLINE] <https://www.nihr.ac.uk/nihr-in-your-area/kent-surrey-and-sussex/patient-and-public-involvement-and-engagement.htm>. Accessed 3 Dec 2018
11. National Institute of Health Research (no date), *The Research Cycle*, [ONLINE] <https://www.nihr.ac.uk/patients-and-public/how-to-join-in/the-research-cycle/>. Accessed 12 June 2018.
12. National Institute of Health Research (no date), *Approaches to public involvement in research*. <http://www.invo.org.uk/posttypesresource/approaches-to-public-involvement/>. Accessed 12 June 2018.
13. Staniszewska, S et al (2017). *GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research*. British Medical Journal: 358
14. World Bank (2018), *World Bank Country and Lending Groups*, [ONLINE] <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519>. Accessed 22 Dec 2018

15. Mushi, D. (2010). *Effectiveness of community based safe motherhood promoters in improving the utilization of obstetric care. The case of Mtwara Rural District in Tanzania.* BMC Pregnancy and Childbirth; 10:14
16. Owolabi, MO. (2014). *Tailored Hospital-based Risk reduction to Impede Vascular Events after Stroke (THRIVES) study: qualitative phase protocol.* Critical Pathways in Cardiology, 13(1):34
17. Bradley, HA and Puoane, T. (2007). *Prevention of hypertension and diabetes in an urban setting in South Africa: Participator Action Research with Community Health Workers.* Ethnicity and Disease, 17(1): 49-54
18. Zola, EK. (2014), *Factors associated with HIV voluntary disclosure of people living with HIV to their steady sexual partner in the Democratic Republic of the Congo: results from a community-based participatory research.* The Pan-African Medical Journal, 14 (19)
19. Aitaoto, N et al. (2015). *Formative research to inform nutrition interventions in Chuuk and the U.S. Pacific.* Journal of the Academy of Nutrition and Dietetics, 115(6): 947-53
20. Hann, K et al (2015), *Factors for success in mental health advocacy,* Global Health Action: 8
21. Jongudomkarn, D (2014). *A volunteer alcohol consumption reduction campaign: participatory action research among Thai women in the Isaan region.* Asian Pacific Journal of Cancer Prevention, 15(17): 7343-50
22. Hayashi, K et al (2012), *Collective Empowerment While Creating Knowledge: A Description of a Community-Based Participatory Research Project With Drug Users in Bangkok, Thailand.* Substance Use and Misuse, 47(5): 502-510
23. Foster, J et al (2010), *A Community-Based Participatory Research approach to explore community perceptions of the quality of maternal-newborn health services in the Dominican Republic.* Midwifery, 26(5): 504-11
24. Liu, J et al (2011). *Community-based participatory research (CBPR) approach to study children's health in China: Experiences and reflections.* International Journal of Nursing Studies, 48(7): 904-913
25. Mosavel, M et al (2005). *Community-based participatory research (CBPR) in South Africa: Engaging multiple constituents to shape the research question,* Social Science and Medicine, 61(12): 2577
26. Bowling, J et al. (2016), *Perceived health concerns among sexual minority women in Mumbai, India: an exploratory qualitative study.* Culture, Health and Sexuality, 18(7): 826-840
27. Grinker, RR et al. (2012). *"Communities" in Community Engagement: Lessons Learned from Autism Research in South Africa and South Korea.* Autism Research, 5(3): 203
28. Simwinga, M et al (2016). *Implementing Community Engagement for Combination Prevention: Lessons Learnt From the First Year of the HPTN 071 (PopART) Community-Randomized Study.* Current HIV/AIDS Report, 13 (4): 194-201
29. Adhikari, B et al. (2017). *Factors associated with population coverage of targeted malaria elimination (TME) in southern Savannakhet Province, Lao PDR.* Malaria Journal, 16:424
30. Fujiwara, T et al (2005), *The spread of drug abuse in rapidly urbanizing communities in Vientiane, Lao People's Democratic Republic,* Health Promotion International, 20(1): 61-8
31. Karmaliani, R et al. (2009), *Applying community-based participatory research methods to improve maternal and child health in Karachi, Pakistan.* Nursing Outlook, 57(4): 204-9
32. Kobeissi, L et al (2011). *Evaluating a Community Based Participatory Approach to Research with Disadvantaged Women in the Southern Suburbs of Beirut.* Journal of Community Health, 36(5): 741-7
33. Wellcome Trust (no date), *Planning your public engagement* [ONLINE]
<https://wellcome.ac.uk/funding/guidance/planning-your-public-engagement>. Accessed 3 Dec 2018
34. National Institutes of Health (NIH) (no date), *Community Engagement*, [ONLINE],
<https://www.nih.gov/health-information/nih-clinical-research-trials-you/community-engagement>. Accessed 3 Dec 2018

35. Australian Government: Department of Foreign Affairs and Trade (2012), *ADRAS Guidelines* [ONLINE], <https://dfat.gov.au/about-us/publications/Documents/adras-guidelines-2012.pdf>
36. UNC Center for AIDS Research (UNCCAF), (no date), *Strategic Community Engagement Education Dissemination (SCEED) Office*, [ONLINE], <http://unccfar.org/portfolio/strategic-community-engagement-education-dissemination-sceed-office/>, Accessed 3 Dec 2018
37. Mockford C et al (2011). *The impact of patient and public involvement on UK NHS healthcare: a systematic review*. International Journal for Quality in Health Care, 24 (1), 28-38
38. Brett J et al (2010). *The PIRICOM Study: A Systematic Review of the Conceptualisation, Measurement, Impact and Outcomes of Patients and Public Involvement in Health and Social Care Research*. Warwick: University of Warwick
39. Brett, J et al. (2012). *Mapping the impact of patient and public involvement on health and social care research: a systematic review*. Health Expectations, 17 (5): 637-650
40. Domecq, JP. (2014). *Patient engagement in research: a systematic review*. BMC Health Services Research, 14:89
41. Maman, S et al (2009), *Using a participatory mapping to inform a community-randomised trial of HIV counselling and testing*. Field Methods, 21(4)368-87
- Minkler, M. (2005) *Community-based research partnerships: Challenges and opportunities*. Journal of Urban Health, 82 (suppl 2), ii3-ii12
42. Campbell M, et al (2015). *Exploring researchers' experiences of working with a researcher-driven, population-specific community advisory board in a South African schizophrenia genomics study*, BMC medical ethics
43. Ntshanga, SP et al (2010). *Establishment of a Community Advisory Board (CAB) for tuberculosis control and research in the Inanda, Ntuzuma and KwaMashu (INK) area of KwaZulu-Natal, South Africa*. Health Policy; 95(2-3):211-5
44. Remien RH, et al (2013). *Masivukeni: Development of a Multimedia Based Antiretroviral Therapy Adherence Intervention for Counselors and Patients in South Africa*. AIDS Behav, 17(6):1979-91
45. Beresford, P. (2002), *User Involvement in Research and Evaluation: Liberation or Regulation?* Social Policy & Society. 1(2): 95–105
46. Gamble, C et al (2015). *An evidence base to optimise methods for involving patient and public contributors in clinical trials: a mixed methods study*. Health Service and Delivery Research (339) NIHR Journals Library: Southampton.
47. Lorway, R et al (2014). *Going beyond the clinic: confronting stigma and discrimination among men who have sex with men in Mysore through community-based participatory research*. Critical Public Health, 24(1); 73-87
48. Morisky, DE et al (2010). *Reducing sexual risk among Filipina female bar workers: effects of a CBPR-developed structural and network intervention*. AIDS Educ Prev, 22(4): 371-85
49. Nichter, M et al (2015). *Developing a smoke free homes initiative in Kerala, India*. BMC Public Health; 15:480
50. Baptiste, DR et al (2006), *Community Collaborative Youth-Focused HIV/AIDS Prevention in South Africa and Trinidad: Preliminary Findings*. J Paediatric Psychology, 31(9): 905-16
51. Blanchard, AK et al (2017). *Pursuing Authenticity From Process to Outcome in a Community-Based Participatory Research Study of Intimate Partner Violence and HIV Vulnerability in North Karnataka, India*. Qual Health Res. 27(2):204-214
52. Bagley, HJ et al. (2016), *A patient and public involvement (PPI) toolkit for meaningful and flexible involvement in clinical trials*. Research Involvement and Engagement, 2:15
53. Cartwright, J. Crowe, S. (2011) *Patient and Public Involvement Toolkit*. BMJ Books
54. Scottish Health Council (June 2018). *The Participation Toolkit* [ONLINE] http://www.scottishhealthcouncil.org/patient_public_participation/participation_toolkit/the_participation_toolkit.aspx#.VZvZybFwbIU. Accessed 12 June 2018

55. Shanks, L et al (2015). *“Losing the tombola”: a case study describing the use of community consultation in designing the study protocol for a randomised controlled trial of a mental health intervention in two conflict-affected regions*. BMC Medical Ethics, 16:38

56. Pardo, G et al (2017). *Cultural Adaptation of an Evidence-Informed Psychosocial Intervention to Address the Needs of PHIV+ Youth in Thailand*. Glob Soc Welf, 4:209

Images

Figure 1 – National Institute of Health Research (no date), *The Research Cycle*, [ONLINE] <https://www.nihr.ac.uk/patients-and-public/how-to-join-in/the-research-cycle/>. Accessed 12 June 2018.

For peer review only

Figure 1: NIHR Research Cycle, NIHR Involve, <http://www.involve.nihr.ac.uk>.

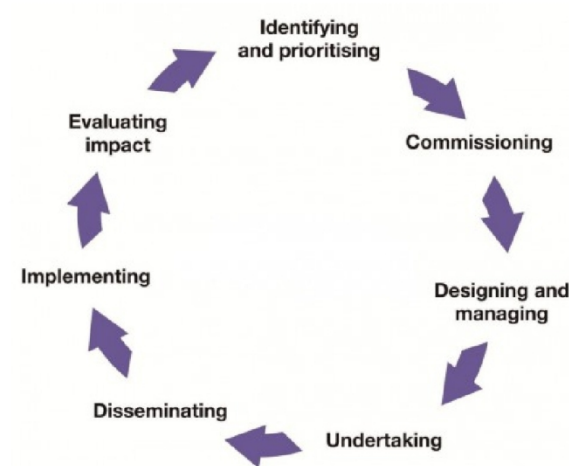


Figure 1 - NIHR Research Cycle

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Figure 2: PRISMA Flow diagram

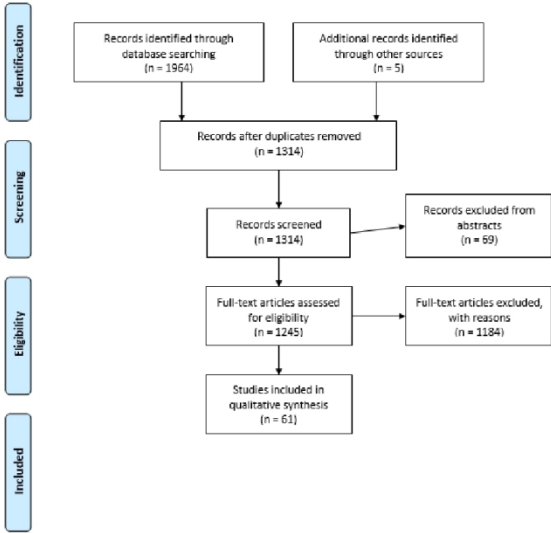


Figure 2 - PRISMA flow diagram
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Figure 3: Details of exclusion criteria

Reason	Number of studies
Not a LMIC	263
Not health research	247
No PPI	358
PPI Theory	157
Ethics Research	101
Patient/Community Engagement	46
Service Development	10
Not in English	1
Duplicate (not picked up in initial duplicate removal)	1
Total = 1184	

Figure 3 - Details for Exclusion Criteria
104x148mm (300 x 300 DPI)

Appendix 1: Included Studies				
Author (s)	Study	Country and Study Design	PPI	Impact
Consultation				
Adhikari, B et al (2017)	Factors associated with population coverage of targeted malaria elimination (TME) in southern Savannakhet Province, Lao PDR. Malaria Journal, 16:424	Laos: Quantitative survey	Trained villagers coordinated community meetings - inform and seek their opinions	Garner trust and participation, adapt subsequent activities, tackled rumours in community, local ownership
Campbell M, et al (2015)	Exploring researchers' experiences of working with a researcher-driven, population-specific community advisory board in a South African schizophrenia genomics study, BMC Medical Ethics	South Africa: Community advisory boards reflection	Community Advisory Board – discussed ethical concerns and challenges around participant recruitment	Allowed the research team to develop a working relationship and rapport Improved informed consent materials, recruitment strategies and protecting research participants and the community from research-related risks Cultural insights into traditional community beliefs Platform for the research team to bring ethical concerns Promote respect for Xhosa people with schizophrenia
Corneli, AL et al (2007)	Involving communities in the design of clinical trial protocols: The BAN Study in Lilongwe, Malawi. Contemporary Clinical Trials, 28 (1), 59-67	Malawi: Trial design	Identify and modify aspects of the clinical trial protocol	Protocol was modified to achieve cultural acceptability, helped us to determine important additional areas of inquiry
Decat, P et al (2013)	Community embedded reproductive health interventions for adolescents in Latin America: development and evaluation of a complex multi-centre intervention. BMC Public Health, 13:31	Bolivia, Ecuador, Nicaragua: Developing interventions – action research	Community advisory boards- discuss process of understanding and planning the intervention and project objectives	Aim of increasing the efficacy and sustainability of project interventions Helped to identify potential barriers to change and possible ways of managing these challenges Encouraged greater dialogue between the target populations of the project and the consortium members responsible for intervention decision-making Responsive to changing political and socio-cultural contexts
Eftekhari, MB et al (2014)	Mental Health Priorities in Iranian Women: Overview of Social Determinants of Mental Health. Iran J Psychiatry, 9(4): 241-247	Iran CBPR - qualitative survey	Co-ordinated with regional stakeholders and key persons and explained the aim of the study	Strengthened the capability of community stakeholders, empowered them to make decisions that they felt were appropriate Implementation of the program to be modified in response to feedback
Ellen, JM et al (2010)	Community Engagement and Investment in Biomedical HIV	South Africa: Trial design	Findings from multisite focus groups will assist in informing	None mentioned

	Prevention Research for Youth: Rationale, Challenges, and Approaches. J Acquir Immune Defic Syndr. 54 Suppl 1: S7-11		the development and design of future prevention trials for adolescents	
Freudenthal, S et al (2006)	School-based prevention of schistosomiasis: Initiating a participatory action research project in northern Tanzania. Acta Tropica, vol 100, issues 1-2, 79-87	Tanzania: PAR – developing intervention	Village leaders organised one meeting in each village and repeated feedback meetings at the two schools	Obstacles have been identified, problems and solutions discussed among teachers, pupils, community members and our research team Importance of working within existing community structures
Maman, S et al (2009)	Using participatory mapping to inform a community-randomized trial of HIV counseling and testing. Field Methods, 21(4):368-87	Thailand, South Africa, Tanzania, Zimbabwe: Mapping exercise	6–13 members of the community were selected to participate in the mapping exercises	Informed decisions about the research design and intervention related decisions, develop an understanding of the community, lay the foundation for collaborative community research partnerships
Mellins, CA et al (2104)	Adapting Evidence-Based Interventions to Meet the Needs of Adolescents Growing Up with HIV in South Africa: The VUKA Case Example. Glob Soc Welf, 1(3):97-110	South Africa: CBPR - developing intervention	Workgroups consisting of ten consumer consultants (five care-givers and five HIV+ adolescents) and ten providers	Developed a cartoon-based curriculum based on stakeholder feedback Provide feedback on the relevance of the content to their lives and the challenges they faced
Mushi, D et al (2010)	Effectiveness of community based safe motherhood promoters in improving the utilization of obstetric care. The case of Mtwara Rural District in Tanzania. BMC Pregnancy and Childbirth, 10:14	Tanzania: Developing intervention	Preliminary results and the intervention package were presented and discussed in a second community meeting and consequent meetings	Inputs and recommendations were incorporated in the final intervention package
Nichter, M et al (2015)	Developing a smoke free homes initiative in Kerala, India. BMC Public Health; 15:480	India: CBPR - developing intervention	Eight members of the local <i>Mahila Samakhya</i> group received interviewer training	None mentioned
Ntshanga, SP et al (2010)	Establishment of a Community Advisory Board (CAB) for tuberculosis control and research in the Inanda, Ntuzuma and KwaMashu (INK)	South Africa: CAB reflection	Community Advisory Board - inform communities of research findings, prepare the community for participation in the clinical trial	Build strong relationships and sense of trust, promote TB awareness, encourage participation, sensitive to cultural practices, alert researchers of community concerns, educate community

	area of KwaZulu-Natal, South Africa. Health Policy; 95(2-3):211-5			
Olaitan, PB et al (2014)	Recruitment of Yoruba families from Nigeria for genetic research: experience from a multisite keloid study. BMC Medical Ethics, 15:65	Nigeria: Trial design	Keloid patients (patient advisors), community leaders, kings/chiefs and medical directors were engaged to assist the research teams with recruitment strategies	None reported
Owolabi, MO et al (2014)	Tailored Hospital-based Risk reduction to Impede Vascular Events after Stroke (THRIVES) study: qualitative phase protocol. Crit Pathw Cardiol, 13(1):29-35	Nigeria: CBPR - qualitative	Task force included representatives of the Nigerian Stroke Society to review the progress of the community participatory research process	Made recommendations about any local adaptations to facilitate its effectiveness
Pardo, G et al (2017)	Cultural Adaptation of an Evidence-Informed Psychosocial Intervention to Address the Needs of PHIV+ Youth in Thailand. Glob Soc Welf, 4:209	Thailand: CBPR – developing intervention	Focus group to review this first draft of the intervention curriculum	Changes to the intervention curriculum were made to address language, culture, and Thai family life Identification of salient issues and methods to increase engagement
Remien RH, et al (2013)	Masivukeni: Development of a Multimedia Based Antiretroviral Therapy Adherence Intervention for Counselors and Patients in South Africa. AIDS Behav, 17(6):1979-91	South Africa: Developing intervention	HIV-positive clinic patients in South Africa to inform content and curriculum	Defined local contextual issues, such as the need for intervention materials that did not rely on the written word Partnership fostered local ownership and commitment to the intervention Intervention being more accessible, acceptable, and likely to be translated into practice
Shanks, L et al (2015)	“Losing the tombola”: a case study describing the use of community consultation in designing the study protocol for a randomised controlled trial of a mental health intervention in two conflict-affected regions. BMC Medical Ethics, 16:38	Chechen Republic, Congo: Protocol development	Community group - medical professionals, key community members (religious and civil leaders, men/women’s groups) as well as the target patient population Feedback on the acceptability and feasibility of the study design	Receive feedback on the acceptability and feasibility of the study design Inform the community of the study in order to promote participation and ensure understanding of the study in the community Provided information on unanticipated harms to the community, allowing changes to the study Inform the community of the study, and through engaging with them early, helped promote legitimacy and joint responsibility.

Simwinga, M et al (2016)	Implementing Community Engagement for Combination Prevention: Lessons Learnt From the First Year of the HPTN 071 (PopART) Community-Randomized Study. Curr HIV/AIDS Rep, 13(4):194-201	Zambia, South Africa CAB reflection	Study proposal was discussed in the community and municipal forums Study-specific CABs were formed	Concerns and misunderstandings about the study prior to study start were identified CAB members have provided a protective role for community members when incidents have occurred as a result of the study and made useful suggestions to improve the performance of study conduct Resolving tensions between researchers and the community Dispelling myths and rumours
South, A et al (2016)	Models and impact of patient and public involvement in studies carried out by the Medical Research Council Clinical Trials Unit at University College London: findings from ten case studies. Trials, 17:376	Multiple countries Case Study reflection	DART trial - Community representatives on trial steering committee Recruitment and Dissemination	High levels of recruitment
Tindana, PO et al (2007)	Grand Challenges in Global Health: Community Engagement in Research in Developing Countries. PLoS Med 4(9):e273	Multiple countries Case study reflection	“Community research support groups” (CRSGs) - preparing the local community for participation in specific CAPRISA research projects - issues such as study participant recruitment and retention strategies Navrongo Experiment - community leaders, traditionally known as chiefs - involved them at all stages of implementation.	CRSGs provide community input to CAPRISA investigators on issues such as study participant recruitment and retention strategies, cultural factors that might affect the research initiative, and development of study-specific communication strategies in Zulu
Collaboration				
Adams, LV et al (2016)	Mining for Solutions: Final report on research designed to engage Southern African Miners, Ex-miners, managers and policymakers, clinicians, and communities on tuberculosis to improve	South Africa: CAB reflection	Miners, ex-miners, families, clinicians, managers and policymakers engaged from the earliest stages of research to help shape questions, methods, and contribute to findings	Emphasize the strengths of resources within the community

	healthcare delivery. Annals of Global Health. 82(3), p.328			
Ahari, SS et al (2012)	Community based needs assessment in an urban area; A participatory action research project. BMC Public Health, 12:161	Iran: PAR - needs assessment	Steering committee - university faculty members, health officials, delegates form Farhikhteh NGO and representatives from twelve blocks or districts of the community. Representatives conducted focus groups in their block.	High participation rates in steering committee suggest that it was appreciated by the community and that problems identified through this research truly reflect community opinion
Anticona, C et al (2013)	Easier said than done: challenges of applying the Ecohealth approach to the study on heavy metals exposure among indigenous communities of the Peruvian Amazon. BMC Public Health, 13: 437	Peru: CAB reflection	Delegates from FECONACO (Federation of Native Communities of the Corrientes River) - two indigenous leaders. - elaborate the study protocol and provide resources to conduct the fieldwork.	Facilitate communications with the communities Gained knowledge of various health topics as well as skills. Hopefully, they will disseminate that learning and carry it forward into their future occupations.
Asante, KP et al (2013)	Community engagement in biomedical research in an African setting: the Kintampo Health Research Centre experience, BMC Health Services Research, 13:383	Ghana: CAB reflection	Community durbars (groups) before, during and after all study implementations - discuss study related issues, areas of research interest	Misconceptions about KHRC and its research activities were identified and clarified. Improve communication guidelines with the community, thus improving on the design and implementation of research.
Balagopal, P et al (2012)	A Community-Based Participatory Diabetes Prevention and Management Intervention in Rural India Using Community Health Workers. Diabetes Educ, 38 (6): 822-34	India: CBPR – developing intervention	Involve community stakeholders in the planning, implementation, education, and review process. Eight preplanning community meetings - identified chronic diseases as an area of concern. The recruiting committee for community health workers consisted of the principal investigator, 2 local village elders, and the project coordinator.	Help to identify the challenges, successes, and lessons learned and to better understand the socioeconomic factors that affect the burden of diabetes. Helped to tailor scientific content and materials into appropriate intervention strategies Positivism in the community toward the study Elected block spokespersons were able to motivate and support villagers who were resistant to the acceptance of the program idea Forum where the villagers could talk and express their opinion and difficulties freely - study design had to be altered accordingly Build trust, confidence, and rapport with the stakeholders and academic partners.

			Block spokespersons were identified to work with the team.	
Bang & Bang (1991)	Community participation in research and action against alcoholism. World Health Forum; 12(1): 104-9	India: PAR – developing intervention	Problem of alcohol was identified by the community. Research was done by a large number of social activists, leaders, teachers and health workers. Decisions were made with key members of the community. Collective action – members of the community are researchers	Engage and empower
Baptiste, DR et al (2006)	Community Collaborative Youth-Focused HIV/AIDS Prevention in South Africa and Trinidad: Preliminary Findings. J Paediatric Psychology, 31(9): 905-16	South Africa, Trinidad: CBPR - intervention pilot	<p>Community advisory boards</p> <p>S Africa - traditional (tribal leaders by lineage) and political leaders in the targeted neighbourhoods formed a steering committee and selected families to participate in an ethnographic study and intervention pilot. Selected parent/caregivers who participated in redesigning intervention sessions to serve as facilitators in the program pilot.</p> <p>T&T - parents and individuals working in HIV/AIDS prevention activities or youth-centered fields to join agency staff to form an advisory board which recruited facilitators to pilot the intervention with families. Early adolescents and parent/caregivers participated</p>	<p>Enhance participants' receptivity to prevention messages</p> <p>Ensure that the project was in the communities' interests</p> <p>Review the program, curriculum, and materials, and to make initial revisions</p> <p>Oversee cultural adaptation of the CHAMP intervention</p>

			in a pilot of the intervention and gave feedback that informed another revision. Researchers collated and disseminated suggested revisions to members of the advisory board for additional review.	
Bisung, E et al (2015)	Using Photovoice as a Community Based Participatory Research Tool for Changing Water, Sanitation, and Hygiene Behaviours in Usoma, Kenya. BioMed Research International, vol. 2015, Article ID 903025, 10 pages.	Kenya: CBPR-developing tool	Community baraza (meeting) - discuss the broad objectives of the research and seek approval from community leaders. Village elder elected to work with the research team - facilitate access to and recruitment of participants Baraza to share the preliminary results and elicit feedback + opportunity to discuss ways of finding sustainable community led solutions	Enhance rigour Facilitate access to and recruitment of participants
Blanchard, AK et al (2017)	Pursuing Authenticity From Process to Outcome in a Community-Based Participatory Research Study of Intimate Partner Violence and HIV Vulnerability in North Karnataka, India. Qual Health Res. 27(2):204-214	India: CBPR - qualitative	Collaboration between non-governmental partners and the community-based organization (CBO) with researchers Community leaders top research priority was to better understand IPV facing their members. Community Research Committee was then formed by women in sex work who volunteered to be involved Research Committee decided key areas that could form themes for the interview guide,	Feedback led to changes in study design Involvement of peer interviewers carried inherent value by buttressing the work and relationships of the CBO to address the daily issues affecting their community Ability to inform decisions, express opinions, and choose to continue being involved in the research or not

			shared space for dialogue on appropriate research questions, methods, ethics, and quality	
Bowling, J et al (2016)	Perceived health concerns among sexual minority women in Mumbai, India: an exploratory qualitative study. <i>Cult Health Sex</i> , 18(7):826-40. doi: 10.1080/13691058.2015.1134812.	India: Qualitative	Partnership with an advocacy organisation, the Humsafar Trust (HST) Protocols edited by the HST ethics review board. The interview and FGD (focus group discussion) protocols were developed in collaboration with HST. We discussed findings from an initial literature review and HST's field experiences. The FGD and the interviews were conducted by a female volunteer from HST	The partnership with local researchers and community partners strengthened the quality of the findings through their involvement in design, recruitment and interpretation phases.
Bradley, HA et al (2007)	Prevention of hypertension and diabetes in an urban setting in South Africa: Participatory Action Research with Community Health Workers, <i>Ethn Dis</i> . 17(1):49-54.	South Africa: PAR – developing intervention	Community voiced concerns to CHWs about the increasing prevalence of hypertension and diabetes in their community. Aims and methods of the project were then formulated to engage CHWs as partners in many aspects of the research process Researchers and CHWs participated in collecting, collating, and analyzing results of the assessment. A summary of the key findings was presented to the local meeting.	CHWs proposed starting a walking club in their area Importance of involving local people in community-based initiatives to promote health CHWs would be empowered In-depth understanding of the complex issues facing this community and the sociocultural factors
Brooks, C et al (2007)	Introducing visual participatory methods to develop local knowledge on HIV in rural South Africa. <i>BMJ Glob Health</i> . 28;2(3)	South Africa: PAR methods	Engaged with communities and health systems stakeholders to develop research questions, interpret data and write up findings	Shared accountability Improve staff–patient relationships - may address the issues identified related to stigma and blame Elicit local knowledge

Ekirapa-Kiracho, EE et al (2016)	Unlocking community capabilities for improving maternal and newborn health: participatory action research to improve birth preparedness, health facility access, and newborn care in rural Uganda. BMC Health Services Research. BMC series2016 (Suppl 7:638)	Uganda: PAR – developing intervention	Stakeholders identified problems and suggested solutions; the program was then adjusted based on these suggestions	None mentioned
Foster, J et al (2010)	A Community-Based Participatory Research approach to explore community perceptions of the quality of maternal-newborn health services in the Dominican Republic. Midwifery, 26(5): 504-11	Dominican Republic: Qualitative	Research topic was outcome of a continuing international partnership between US midwives and Dominican nurses Four community leaders in research team – involved in coding and gave a public presentation with the Dominican nurses	Team continue to meet together regularly with hospital and community volunteers to articulate how to implement improvements in the maternity setting
Fujiwara, T et al (2005)	The spread of drug abuse in rapidly urbanizing communities in Vientiane, Lao People's Democratic Republic. Health Promot Int, 20(1), 61-8	Laos: Qualitative	Entire process from planning to implementation was shared with local partners Developed a consensus on the objectives of the survey together with local governors and village leaders Questionnaire was tested first on the neighbourhood leaders, and they were therefore trained to conduct interview surveys in workshops	Raising awareness and in facilitating community activities to prevent drug abuse, increasing the quality of information obtained, required a considerable amount of time, positive influence on the development of programs to prevent drug abuse
Gaudine, A et al (2007)	An Action Research Approach to Developing Culturally Relevant Interventions: The Stigma of HIV in a Vietnamese Community. Can J Nurs Res, 39(3): 195-7	Vietnam: PAR – developing intervention	Faculty members formed an advisory committee of 10 key members of the community and helped them to reach consensus on the issue to be addressed	None mentioned

			Summarized the data for the advisory committee and agreed on community interventions	
Grinker, RR et al (2012)	"Communities" in Community Engagement: Lessons Learned from Autism Research in South Africa and South Korea. Autism Res, 5(3): 201-210	South Africa, Korea Developing intervention	Researchers engaged communities in a research protocol, adapted and translated screening and diagnostic tools, and developed methods for screening, evaluating, and diagnosing children with ASD Researchers and focus group participants worked together to craft the confidentiality procedures. Focus groups discussions of specific components of the research (for example, consent forms, administration of surveys, and locations for research.	Local knowledge helped researchers to address both ethnographic as well as practical problems Stakeholders objected to the definition of their community Facilitates the crucial recruitment phase as well as participant retention by limiting or managing negative views or misunderstandings of the researchers, procedures or goals of the study, though the process may be slow Feedback from the focus groups was used to guide and revise the study procedures
Jacobs, B et al (2003)	Community participation in externally funded health projects: Lessons from Cambodia. Health Policy Plan; 18(4):399-410	Cambodia: CAB reflection	Community Participation Advisory Committee	Guide on cultural and political appropriateness and to ensure the active participation of pagoda volunteers in health-related issues.
Karmaliani, R et al (2009)	Applying community-based participatory research methods to improve maternal and child health in Karachi, Pakistan. Nurs Outlook; 57(4):204-9	Pakistan: CBPR – developing intervention	Focus group Involved the community as appropriate in the research process, including defining and validating the health problem, intervention design, and site and participant selection.	The process of collaboration between researchers and community residents resulted in the design funding for an economic skill building intervention Increased time required
Kobeissi, L et al (2011)	Evaluating a Community Based Participatory Approach to Research with Disadvantaged	Lebanon: CBPR - qualitative	Community advisory committee (CAC - one governmental and two major	Ensure that the research had scientific relevance was reflective of the women's needs, was feasible, and culturally acceptable Strengthen the sense of ownership

	Women in the Southern Suburbs of Beirut. J Community Health, 36(5): 741-7		non-governmental organizations), a local women committee (LWC - nurses, social workers, midwives as well as laywomen from the community) Contributed to joint decision making and advised on supporting local initiatives Recruitment campaign was spearheaded by the LWC Oversaw the planning and implementation of the intervention Guided the development of: study instruments, informed consent forms, the intervention package, the recruitment campaign, as well as the implementation phase	Building trust and rapport Labour intensive and time-consuming
Lee, K et al (2015)	Sexual and reproductive health services for women with disability: a qualitative study with service providers in the Philippines. BMC Womens Health, 15:87	Philippines: PAR - qualitative	The question guides were developed and trialled in a participatory workshop involving co-investigators and W-DARE partners, and were informed by the experiences of women with disability. Data analysis workshop with co-investigators and W-DARE partners including women with disability, SRH service providers and gender specialists Initial coding framework was collaboratively developed by workshop participants and refined by the first author	None mentioned
Liu, J et al (2011)	Community-based participatory research (CBPR) approach to	China: CBPR –	Partnership includes health workers from 3 governmental	Modified the wording of some of the items in the original translated versions of the CBCL to ensure cultural relevance for a Mandarin-

	study children's health in China: Experiences and reflections. Int J Nurs Stud; 48(7):904-13	reflection	public health and medical agencies, parents and teachers from 4 community schools, and academic researchers from 4 universities. Steering committee - formed to guide the project's decision making and research process Researchers responded to inquiries regarding concerns about the health impact of nutrition and lead exposure Community partners actively participated in developing research protocol, field works, and finding dissemination	speaking population.
Lorway, R et al (2014)	Going beyond the clinic: confronting stigma and discrimination among men who have sex with men in Mysore through community-based participatory research. Critical Public Health, 24(1); 73-87	India: CBPR - qualitative	Community advisory committee - leaders from local community-based organizations CRs (community researchers) formulated recruitment procedures and were trained to approach members of their community using a recruitment script. Two community leaders formulated a tentative interview guide CRs reviewed five of the transcripts and compiled a list of significant themes	Empowering Sensitively confronted and overcome stigma
Makhoul, J et al (2014)	Community-based participatory research in complex settings: clean mind-dirty hands. Health Promot Int, 29(3):510-7	Lebanon: CBPR - reflection	Community youth coalition Coalition reviewed conceptual frameworks and published evidence, did a priority setting exercise Coalition developed a logic model for the intervention	Creates a platform for them to express their concerns in the planning and implementation processes

			and then conducted qualitative interviews Findings of the outcome evaluation were presented in coalition meetings where plans for further analysis and interpretation were made.	
Massey, PD et al (2012)	TB questions, East Kwaio answers: community-based participatory research in a remote area of Solomon Island. Rural Remote Health, 12:2139	Solomon Island: CBPR - qualitative	Community and church leaders Chief part of interview team	None mentioned
Morisky, DE et al (2010)	Reducing sexual risk among Filipina female bar workers: effects of a CBPR-developed structural and network intervention. AIDS Educ Prev, 22(4): 371-85	Philippines: CBPR – developing intervention	Partnership - lay community members, organizational representatives (including nongovernmental organizations), and academic researchers Equal roles in helping to develop and implement each of the interventions and evaluate the study Conducted needs analysis in each community. Developed the interviewer's guide Subcommittee of the CBPR partnership analyzed the interview data to identify themes	Refine the study design, determine best methods for data collection and intervention implementation, and finalize the trainings
Mosavel, M et al (2005)	Community-based participatory research (CBPR) in South Africa: Engaging multiple constituents to shape the research question. Soc Sci Med; 61(12):2577-87	South Africa: CBPR – trial design	Identifying the concerns and priorities of the community Community-based “reference team” = providing the community with a forum for shaping, commenting on, critiquing, and helping to guide our research.	Developed a research framework that incorporated the community’s concerns and priorities Involved in the decision to conduct focus groups and in ongoing discussions about the future direction Re-focus our research from cervical cancer to ‘cervical health’

Murray, LK et al (2013)	Identification, modification, and implementation of an evidence-based psychotherapy for children in a low-income country: the use of TF-CBT in Zambia. <i>Int J Ment Health Syst</i> ; 7:24	Zambia: CBPR – developing intervention	Intervention selection included joint meetings with stakeholders, review of qualitative research, and review of the literature. Met with local stakeholders to share the results of the qualitative study. Stakeholders identified a void of services for moderate to severe symptoms following child abuse. Stakeholders discuss treatment options and collaboratively chose TF-CBT as the intervention.	Local community input is critical to understanding what is currently available and used in the community, as well as potential interventions that might “fit.”
Nyamathi, AM et al (2010)	Perceptions of Women Living with AIDS in Rural India Related to the Engagement of HIV-Trained Accredited Social Health Activists for Care and Support. <i>J HIV AIDS Soc Serv</i> , 9(4):385-404	India: CBPR - qualitative	Community advisory board Reviewed the outcomes of the focus group discussions Assisted in the refinement of the interview guide used in the focus groups Board helped shape the intervention program which was being designed	Assist researchers in understanding the nature of delivering HIV/AIDS care in rural areas, as well as the barriers and facilitators of offering support to WLA. Culturally sensitive Ensured knowledge of the social and cultural perspectives and experiences of the target population Assisted in the refinement of the interview guide used in the focus groups
Pazoki R, et al (2007)	Effects of a community-based healthy heart program on increasing healthy women's physical activity: a randomized controlled trial guided by Community-based Participatory Research (CBPR). <i>BMC Public Health</i> , 7:216	Iran: CBPR - RCT	Twelve group sessions were conducted to find out community priorities in health research Community advisory board - members of Bushehr Province helped develop the educational curriculum, reviewed training program material, guide the nature and structure of the intervention	Tailoring the study to the target community CAB reduced the duration of intervention from 12 weeks to 8 weeks Empowering the community More reflective conclusion drawing processes
Puffer ES, et al (2013)	Developing a Family-Based HIV Prevention Intervention in Rural Kenya: Challenges in Conducting	Kenya: CBPR - Reflection	Community advisory committee involved during formative research, intervention	Knowledge of the culture and local norms

	Community-Based Participatory Research. J Empir Res Hum Res Ethics, 8(2):119-28		development, and a pilot trial. Collaborated to develop the initial research questions and interpreted these results . Series of collaborative meetings to identify targets of the intervention and to develop an implementation plan. CAC members took on roles as intervention facilitators or survey enumerators.	
Ramjee G, et al (2010)	Experiences in conducting multiple community-based HIV prevention trials among women in KwaZulu-Natal, South Africa. AIDS Res Ther, 7:10	South Africa: Trial reflection	Community Working Groups Facilitated the recruitment process Dissemination of trial results	Represent the voice and interests of the community throughout the research process Useful in formulation of a suitable language lexicon, messaging, and dissemination of trial results Community education Networking facilitated the recruitment process Contributed to acceptance of the IC (informed consent) process instituted in our trials
Rhodes, SD et al (2015)	The ecology of sexual health of sexual minorities in Guatemala City. Health Promot Int, 30(4):832-42	Guatemala: CBPR - qualitative	Partnership included a gay Guatemalan university professor, three local gay business owners and three Guatemalan gay men Involved in each step of the research process—from conception to study design and conduct, data analysis and interpretation, and dissemination of findings Development of standardised guides	Leads to increased insightfulness and subsequent use of findings
Twine, R et al (2016)	Involvement of stakeholders in determining health priorities of adolescents in rural South Africa. Global Health Action; 9	South Africa: Research priorities	Determine adolescent health priorities according to key stakeholders Stakeholder forum determined root causes, agreed that	Ensures that stakeholders are on board in appreciating the pertinence of the research Increases awareness Can tease out issues, helping to shape, refine, and ensure that later stages of intervention development are targeted appropriately

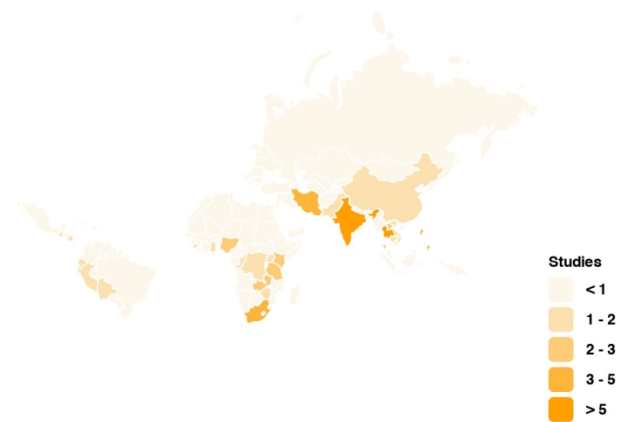
			intervention needs to focus on behavioural change and improving health literacy There will be continuous involvement of the stakeholder forum	Stakeholders could become, or engage with, policy 'champions' to act on research findings
Vaughan, C et al (2015)	W-DARE: a three-year program of participatory action research to improve the sexual and reproductive health of women with disabilities in the Philippines. BMC Public Health; 15:984	Philippines: PAR - mixed methods	Local women with disabilities, their representative organisations, and SRH service providers will be involved as members of the research team across all stages of the research including initial design, development of research tools and processes, collection and analysis of data, design and implementation of interventions, and drafting of guidelines Fieldwork teams will include women and men with disability - qualitative data collectors Analysis of data will be done collaboratively	None mentioned
Wattthayu, N et al (2015)	Applying Qualitative Data Derived from a Rapid Assessment and Response (RAR) Approach to Develop a Community-based HIV Prevention Program for Adolescents in Thailand. J Assoc Nurses AIDS Care; 26(5):602-12	Thailand: Qualitative and developing intervention	Project was led by a community advisory board (CAB) made up of local officials and leaders of the local health care community Adolescent and adult community-stakeholder focus groups were used to gain input for the design of an HIV prevention program Forum for expressing ideas, opinions, and concerns associated with the development of a cultural- and	Cultural- and age-appropriate

			age-appropriate HIV prevention program	
Zola, EK et al (2014)	Factors associated with HIV voluntary disclosure of people living with HIV to their steady sexual partner in the Democratic Republic of the Congo: results from a community-based participatory research. Pan Afr Med J; 19:276. doi:10.11604/pamj.2014.19.276.5304	Democratic Republic of Congo CBPR - qualitative	CBOs (community based organisation) members, PLHIV (people living with HIV) and researchers were involved, in an equitable partnership Community members were trained to research methods and research ethics Results of the project were presented to participants and stakeholders The questionnaire was developed by the whole team Participants were interviewed face-to-face by CBO members	Gave a voice to the community about a very sensitive issue Fruitful exchanges of experience and mutual empowerment
User-Led				
Aitaoto, N et al (2015)	Formative research to inform nutrition interventions in Chuuk and the U.S. Pacific. J Acad Nutr Diet, 115 (6): 947-53	Micronesia: CBPR - qualitative and developing intervention	Faith in Action Research and Resource Alliance (FARRA) selected the research topic, participants, sites and scientific research partner Two representatives assisted in the development of research tools, data collection and analysis. Two community organizational partners assisted with recruitment and data collection logistics.	Culturally appropriate
Hann, K et al (2015)	Factors for success in mental health advocacy. Glob Health Action, 17:8	Sierra Leone: CBPR - qualitative	Membership from service users and their family members, service providers, non-governmental organisations (NGOs), government officials, and civil society	Capacity building Advice of the Community Advisory Board regarding recruitment Context-specific ethical guidance

			<p>Members of the MHC (mental health coalition advocacy group) designed and carried out the study</p> <p>Research questions were developed collaboratively with the study team and other members of the MHC</p> <p>Involved in data collection</p> <p>Community Advisory Board</p>	
Hayashi, K et al (2012)	<p>Collective Empowerment While Creating Knowledge: A Description of a Community-Based Participatory Research Project With Drug Users in Bangkok, Thailand. <i>Subs Use Misuse</i>, 47(5):502-510</p>	Thailand: CBPR - reflection	<p>Group of active and former drug users =Thai Drug Users' Network (TDN)</p> <p>Two members of the local community organization involved in gathering data and validated draft summaries of the results.</p> <p>They helped design the overall study, and were trained in various aspects of research</p> <p>Survey instrument was designed in consultation with the peer researchers</p> <p>Debriefing session to discuss the plan for data analysis and output - division of labor was discussed</p> <p>All the data were presented to the community before being released publicly</p> <p>Peer researchers continue to be involved in ongoing data analysis, interpretation of data, and dissemination of study findings.</p>	<p>Confirming that the interpretation of the data was in line with the local knowledge.</p> <p>Affected the timing and budget of the project</p> <p>Helped ensure the smooth implementation of the project</p> <p>Through consultation with the peer researchers, it was decided that no identifying information would appear on questionnaires</p> <p>Peer researchers - improved communication skills</p> <p>Hoped to continue the outreach activities</p> <p>Quickly accessing a hard-to-reach population</p>

Jongudomkar n, D (2014)	A Volunteer Alcohol Consumption Reduction Campaign: Participatory Action Research among Thai Women in the Isaan Region. Asian Pac J Cancer Prev. 2014;15(17):7343- 50.	Thailand: PAR - qualitative	The women participants were involved in the entire research process. Research initiated by community members via a community forum. Analysis and interpretation of the data were presented to the participants, they developed a strategic plan and an action plan, together with a continuing evaluation process.	After the conclusion of the project, these women became resource persons responsible for alcohol consumption campaigns. Empowering Increased self-esteem Capacity and confidence-building skills
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Appendix 2: Number of studies in low- and middle-income countries



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PRISMA 2009 Checklist

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Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3-4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	n/a
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	5
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5-6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5-6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	n/a
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	6
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I ²) for each meta-analysis.	6



PRISMA 2009 Checklist

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	n/a
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	n/a
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6 + appendix 2
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	n/a
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Appendix 2
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	6-8
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	n/a
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	9-12
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	2, 9-12
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	12-13
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	13

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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